Title

Examining the impact of a multimedia intervention on decisional conflict and psychological distress among early-stage breast cancer patients: results from a nationwide RCT.

Journal

Translational Behavioral Medicine, 13(10)

Authors

Marziliano, Allison
Miller, Suzanne
Fleisher, Linda
et al.

Publication Date

2023-09-28

DOI

10.1093/tbm/ibad037

Peer reviewed

Translational Behavioral Medicine, 2023, **13**, 727–735
https://doi.org/10.1093/tbm/ibad037
Advance access publication 28 June 2023
Original Research

TBM OXFORD

Examining the impact of a multimedia intervention on decisional conflict and psychological distress among early-stage breast cancer patients: results from a nationwide RCT

Allison Marziliano,[1] Suzanne M. Miller,[2] Linda G. Fleisher,[2] Mary E. Ropka,[3] Annette L. Stanton,[4] Kuang-Yi Wen,[5] Talea Cornelius,[6] Emmanuel Lapitan,[2] Michael A. Diefenbach[1]

[1]Institute of Health System Science, The Feinstein Institutes for Medical Research, Northwell Health, Manhasset, NY, USA
[2]Cancer Prevention and Control Program, Fox Chase Cancer Center, Temple University Health System, Philadelphia, PA, USA
[3]Public Health Sciences, University of Virginia School of Medicine, Emeritus, Charlottesville, VA, USA
[4]Departments of Psychology and Psychiatry/Biobehavioral Sciences, University of California, Los Angeles (UCLA), Los Angeles, CA, USA
[5]Division of Population Science, Department of Medical Oncology, Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, PA, USA
[6]Division of General Medicine, Department of Medicine, Columbia University, New York, NY, USA
Correspondence to: MA Diefenbach, Mdiefenbach@northwell.edu

Abstract

We conducted a nationwide, randomized controlled trial to evaluate the impact of *Healing Choices*, a novel interactive education and treatment decision program rooted in the self-regulation theory framework, on decisional conflict and psychological distress at 2-month post-intervention in women with early-stage breast cancer. Patients were randomized to receive the National Cancer Institute's standard print material (control) or standard print material plus *Healing Choices* (the intervention). The final sample at 2-month post-intervention consisted of N = 388 participants (intervention: n = 197; control: n = 191). There were no significant differences in decisional conflict or its subscales; however, psychological distress was higher in the intervention group (16.09 ± 10.25) than in the control group (14.37 ± 8.73) at follow-up, B = 1.88, 95% CI [−0.03, 3.80], t(383) = 1.94, p = .05. Upon further examination, we found that engagement with the intervention was low—41%—prompting as-treated analyses, which showed no difference in distress between users and nonusers and a positive impact of Healing Choices on decisional conflict: decisional support subscale: users (35.36 ± 15.50) versus nonusers (39.67 ± 15.99), *B* = −4.31 (s.e. = 2.09), *p* = .04. Multiple recommendations for moving ahead stem from this work: (i) intent-to-treat analyses appeared to cause distress, cautioning against interventions that may lead to information overload; (ii) engagement with the intervention is low and future work needs to focus on increasing engagement and monitoring it throughout the study; and (iii) in studies with low engagement, as-treated analyses are critical.

Lay summary

Healing Choices is a multimedia software program that provides information and decision-making support for women with early-stage breast cancer. We present the results of a randomized controlled trial that evaluated the impact of *Healing Choices*, compared with standard of care (National Cancer Institute's standard print material), on decisional conflict and psychological distress. In total, 388 participants (197 in the intervention and 191 in the control group) completed the 2-month post-intervention assessment. Results indicated that *Healing Choices* did not help with treatment decision-making but was associated with higher levels of psychological distress. Use among women assigned to *Healing Choices*, however, was low, at 41%. When comparing women who used the program with those who did not, we found that the effect of elevated distress disappeared, while program users felt more support than nonusers during the decision-making process. In the future, interventions such as *Healing Choices* should be regulated so as not to cause distress via information overload, a focus on monitoring and increasing engagement with the intervention is necessary, and, when engagement is low, as-treated analyses are critical to explore the efficacy of the intervention.

Keywords Breast cancer, Multimedia intervention, Decision-making, Psychological distress

Implications

Practice: Safeguards (e.g., email reminders) and incentives through gamification should be developed and applied to ensure engagement with educational interventions, as well as to balance information provision with recipients' potential distress levels and maximize the efficacy of the intervention.

Policy: Policy efforts are needed to support the development and maintenance of tailored and targeted education and decision tools to facilitate decision-making, across a variety of information channels.

Research: Research is necessary to examine those software elements that are most usable and effective in education, preference identification, and decision-making, among a diverse population facing healthcare procedures.

INTRODUCTION

Breast cancer is the most commonly diagnosed cancer in women (1/8 women in the USA will be diagnosed during their lifetime), as well as the second leading cause of cancer death among women [1]. When diagnosed in the early stages of the disease, the 5-year survival rate is as high as 90% [1]. There are different treatment options for women diagnosed with early-stage breast cancer, including breast-sparing surgery plus radiotherapy, total mastectomy, modified radical mastectomy, lumpectomy, or partial mastectomy. Given the many effective treatment options, each with the potential for adverse side effects, treatment decision-making is complex.

In such situations, value-congruent decisions represent an ideal [2–4]. Value-congruent decisions are achieved through collaborative discussions between providers who share their expertise, and elicit and take into account patients' preferences, expressed as values and goals [2–4]. In practice, however, several barriers to this ideal patient–provider interaction exist. Patients often have difficulties identifying their preferences, based on a lack of understanding of complex medical information; providers are rarely trained in eliciting patients' preferences, and do not have sufficient time or expertise to engage in shared decision-making [5–7].

To enhance shared decision-making, researchers have focused on developing and evaluating evidence-based, interactive multimedia educational programs aimed at facilitating patient education and decision-making, including improving the process of preference elicitation, thereby increasing the occurrence of value-congruent decisions [8, 9]. The content of these programs vary, ranging from simply providing information to preparing patients for surgical procedures [10]. The few studies available show success in improving patients' knowledge of treatment options, decreasing anxiety and cancer-related worry, and increasing patients' confidence when communicating with their physician [10, 11].

The *Healing Choices for Women with Breast Cancer* Program (i.e., "*Healing Choices*") is a novel interactive education and treatment decision aid for patients diagnosed with early-stage breast cancer. The goal of *Healing Choices* is to enhance communication between the patient and their physician and/or healthcare team. The program is based on self-regulation theoretical frameworks, which postulate that cognitive and affective processes guide decision-making. The central postulates of these theories are embedded in *Healing Choices* through the program's focus on providing cancer-relevant information on treatments and side effects, managing patients' expectations about outcomes through peer testimonials and physicians' responses to common questions, providing emotional support to patients with cognitive and self-regulatory exercises to normalize feelings and reduce distress, and modeling effective decision-making skills [12, 13]. The program was also designed to increase patients' continued engagement with the tool, through illustrations, graphics, and videos.

Study purpose

The goal of the study was to evaluate the ability of *Healing Choices* to facilitate treatment decision-making, without elevating distress among patients diagnosed with early-stage breast cancer, in a national randomized controlled trial (RCT). The RCT compared outcomes of patients randomized to standard of care (comparison condition) versus *Healing Choices*, at baseline and at 2-month post-intervention. Given evidence-based findings that engagement with web-based tools can range widely [14, 15], we conducted both intent-to-treat (intervention vs. control) and as-treated analyses (website users vs. nonusers). We hypothesized that patients randomized to *Healing Choices* (intervention condition) would report lower levels of decisional conflict and cancer-related distress compared with patients in the control condition.

METHODS

This manuscript reports on one of three RCTs from the Cancer Information Service Research Consortium (CISRC), in collaboration with the National Cancer Institute's (NCI) Cancer Information Service (CIS) [16]. This project was approved by the Institutional Review Boards (IRBs) of the University of Colorado Denver, Anschutz Medical Campus, as well as the collaborating research institutions (i.e., University of California, Los Angeles, and Fox Chase Cancer Center) and parent institutions of the three CIS contact centers (i.e., University of Miami, Fred Hutchinson Cancer Research Center, and Memorial Sloan Kettering Cancer Center). The trial was registered at clinicaltrials.gov under NCT00830635. The study was conducted between 2009 and the end of 2014.

Procedures

Study participants were women diagnosed with breast cancer who initiated contact with one of the CIS contact centers via telephone (1-800-4-CANCER) to speak with highly trained information specialists about their questions and concerns regarding the diagnosis and treatment of the disease. At the end of the standard call, eligibility and interest in the three CISRC trials were assessed by the CIS specialist and, if applicable, verbal informed consent and a baseline interview were completed over the telephone.

Although the majority of the patients were recruited for these trials through the CIS contact centers, additional recruitment sites and strategies were added to facilitate timely recruitment. These sites included a newly established call center from the

CISRC at the University of Colorado Cancer Center, a collaboration with the American Cancer Society's call center (where cancer education specialists were trained by study personnel), flyers and print materials, CISRC websites, radio, outreach, and word-of-mouth. With the exception of the ACS call center, none of the other methods of recruitment contributed substantially to our sample size. We conducted a chi-square comparing, within the intervention arm, our two main methods of recruitment (CIS vs. American Cancer Society) and found no significant difference in usage by recruitment method, $p = .634$.

Inclusion/exclusion criteria

To be eligible to participate, individuals had to meet the following criteria: (i) newly diagnosed, defined as having received a diagnosis within the past 60 days, with nonmetastatic breast cancer, (ii) female, (iii) access to a computer either personally or through a family member/friend, (iv) speak English, (v) provide telephone informed consent, and (vi) had not yet made a treatment decision. Patients were excluded from participation if they had completed treatment for breast cancer or had another primary tumor or cancer recurrence.

Randomization

Following screening, consent, and the baseline interview, participants were randomized to either Group 1 (Control condition) or Group 2 (*Healing Choices*, intervention condition). Those in Group 2, the *Healing Choices* intervention condition, were given access to *Healing Choices* but decided for themselves whether or not they wanted to use the program.

Group 1 (Control condition)

Those randomized to Group 1 received personalized information about breast cancer, treatment options, potential side effects, and existing clinical trials, provided during their telephone call. In addition, they received NCI standard print material ("What You Need to Know about Breast Cancer" and "Surgery Choices for Women with Early Stage Breast Cancer," NIH Publication Numbers 12-1556 and 04-5515, respectively) shipped via express mail and received within 24–48 hr of their call. The print materials mailing included an introductory letter to the study.

Group 2 (Healing Choices intervention group)

Those randomized to Group 2 received identical information as those in Group 1 (information via a telephone call, NCI print materials, and an introductory letter). In addition, Group 2 received access to *Healing Choices* via CD-ROM as well as information about the program and details on how to access the program via the Internet. Group 2 also received a second follow-up letter 14-day post-enrollment to encourage use of *Healing Choices*. Of note, participants received access to the entire program and were free to explore the different modules as they desired.

The *Healing Choices* program emphasizes values clarification, utilizing the metaphor of a virtual health center to organize and present information in four modules: Library, Patient Stories, Doctor's Office, and a Notebook. The Library module provides books on relevant topics including over 100 pages of NCI-approved text and graphics. The Patient Stories module consists of 5- to 6-min videos of patients, chosen to be representative of different ethnicities and treatment selections, to emphasize the diversity and divergence among real-life patient perspectives. The Doctor's Office module models effective patient–provider communication skills, provides questions to ask the provider, as well as videos of physicians answering frequently asked questions from patients. The Notebook module shows patients how to record, store, and rank information relevant to them as they read through the books in the Library module.

Study assessments

Data were collected by blinded research staff at: (i) baseline/enrollment (pre-intervention) and (ii) 2-month post-intervention.

Baseline/enrollment questionnaire

Baseline measures included demographic (e.g., age, education, race/ethnicity, income, and medical insurance) and clinical characteristics (e.g., cancer stage, comorbidity). Comorbidity was assessed by the Charlson Co-Morbidity scale [17], a widely used measure that accounts for the number and seriousness of comorbid diseases (e.g., liver disease, diabetes) with higher scores indicating higher comorbidity and illness burden. Cancer-related psychological distress was assessed using the Intrusion subscale of the Impact of Events Scale (IES) [18]. The subscale assessed the experience of being diagnosed with breast cancer and was composed of seven items that were answered on a 4-point Likert scale, according to how often each item had occurred within the past 7 days. The 4 points on the scale are: "Not at all," "Rarely," "Sometimes," and "Often." It has been widely used and has well-established psychometric properties (Cronbach's α in this study = 0.82). A higher score indicates an elevated level of intrusive thoughts about breast cancer, signifying higher distress. Established cut points for the full IES scale are: 0–8 subclinical range, 9–25 mild range, 26–43 moderate range, and 44+ severe range. Based on these estimates, we indicated scores ≥20 on the IES Intrusion subscale to indicate clinically significant or elevated levels of distress [19].

Two-month post-enrollment evaluation

The IES was administered at 2-month follow-up to assess the change in cancer-related psychological distress from baseline. In addition, decisional conflict was assessed using the Decisional Conflict Scale (DCS) [20]. The scale consists of five subscales: Feeling Informed (3 items); Values Clarity (3 items); Decisional Support (3 items); Decisional Uncertainty (3 items); and Effective Decision (4 items). All subscales employ a 5-point Likert response scale from "0—Strongly Agree" to "4—Strongly Disagree." The full scale and the five subscales have strong psychometric properties with a mean alpha coefficient of 0.84 (i.e., Cronbach's α: Full scale = 0.93; Feeling Informed = 0.70; Values Clarity = 0.81; Decisional Support = 0.78; Decisional Uncertainty = 0.79; and Effective Decision = 0.83). A mean score was used to indicate the level of decisional conflict, with higher scores indicating higher levels of conflict.

Website use was captured via self-report at the 2-month follow-up assessment, using the question "Did you use the website, the CD, both the website and CD, or neither of these?" A trained research assistant interviewer administered the question to the participant, and offered binary (yes/no) response options for each category (website, CD, both, neither, did not receive).

Additionally, we used several quantitative questions to assess participants' perception of Healing Choices (i.e.,

increased knowledge about breast cancer/treatment, helped patient talk with doctor about cancer/treatment, helped with emotional concerns, made patient less anxious or upset, etc.).

Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS; [21]) Version 22.0 and SAS (Cary, NC; [22]). Descriptive statistics (mean and SD, or percent) of baseline demographic, clinical, and psychological variables were calculated and, using two-sample t-tests (for continuous) or chi-square and Fisher's exact tests (for categorical), compared across (i) the intervention and control conditions; and (ii) within the intervention condition, users and non-users. Primary outcome analyses on decisional conflict and its subscales (using linear regression) and psychological distress (using linear regression for the IES scale and logistic regression for the percentage cutoff) were conducted with (i) the intent-to-treat analyses (i.e., intervention vs. control); and (ii) as-treated analyses (i.e., within the intervention, users vs. non-users).

RESULTS

Intent-to-treat analyses: comparing *Healing Choices* to control condition

Baseline demographics of the 617 randomized participants (310 to *Healing Choices* and 307 to control condition) are detailed in Table 1. Overall, the majority of the sample was White (80.5%), most had completed college or higher (48.7%), and the average age was 55.50 (*SD* = 11.13). Almost half of the participants (48.6%) reported clinically significant psychological distress due to breast cancer at baseline, based on the validated IES cutoff score [23]. The intervention group included a greater proportion of White participants, compared with non-White participants (p = .06), and those with an income of $80,000 or more ($p$ = .05). Ethnicity and income were included as control variables in subsequent analyses of intervention effects. There were no other significant differences between the two study groups with regard to baseline demographic, clinical, or psychological variables.

Primary outcome analyses included data from participants who completed both the baseline and 2-month assessments and had full data on covariates and study outcomes (N = 388). Differences between the *Healing Choices* intervention and control groups in decisional conflict variables and psychological distress at the 2-month follow-up time point are detailed in Table 2. Results of regression analyses indicated no significant differences in the DCS total score, B = –0.06, 95% CI [–2.74, 2.63], $t(383)$ = 0.04, p = ns, or any of the subscales (uncertainty, B = 0.92, 95% CI [–2.93, 4.77], $t(383)$ = 0.47, p = ns; informed, B = –0.27, 95% CI [–3.93, 3.39], $t(383)$ = 0.15, p = ns; value clarity, B = –0.21, 95% CI [–3.44, 3.02], $t(383)$ = 0.13, p = ns; support, B = .45, 95% CI [–2.72, 3.62], $t(383)$ = 0.78, p = ns; effective decision, B = –1.17, 95% CI [–4.11, 1.77], $t(383)$ = 0.78, p = ns).

Participants in the intervention group reported significantly higher levels of psychological distress at the 2-month

Table 1 | Baseline demographics and clinical characteristics of intervention versus control

	Full sample (N = 617)	Healing Choices (n = 310)	Standard care (n = 307)	t or χ^2	p
	$M \pm SD$ or %	$M \pm SD$ or %	$M \pm SD$ or %		
Age	55.50 ± 11.13	55.11 ± 10.64	55.90 ± 11.60	0.88	.38
Educational level					
High school graduate or less	21.8%	22.6%	21.1%	2.77	.25
Some college	29.5%	26.5%	32.6%		
College graduate or more	48.7%	51.0%	46.4%		
Ethnicity					
Other	3.7%	3.3%	4.1%	5.73	**.06**
African-American	15.8%	12.4%	19.2%		
White	80.5%	84.3%	76.6%		
Income					
<$30,000	34.4%	35.1%	33.7%	8.03	**.05**
$30,000–$59,000	25.2%	20.8%	29.7%		
$60,000–$79,000	11.9%	11.5%	12.3%		
$80,000 or higher	28.5%	32.6%	24.3%		
BMI	28.31 ± 6.69	28.14 ± 6.52	28.48 ± 6.86	0.54	.59
Comorbidity	1.87 ± 2.16	1.83 ± 2.17	1.91 ± 2.16	0.48	.63
Medical insurance	92.4%	91.8%	93.0%	0.23	.64
Baseline psychological distress					
Intrusion subscale	18.69 ± 8.64	18.80 ± 8.50	18.57 ± 8.79	0.32	.75
Clinically significant levels of distress (scores ≥20)[a]	48.6%[a]	47.1%[a]	50.2%[a]	0.59[a]	.44[a]

BMI body mass index; *IES* Impact of Events Scale.

[a] Based on validated case rule of IES scores ≥20 indicating clinically significant or elevated levels of distress.

the bold values indicate statistical significance, p < .05

Table 2 | Means and standard deviations for study outcomes at 2-month post-intervention comparing intervention and control

	Full sample (N = 388[b])	Healing Choices (n = 197)	Standard care (n = 191)	t	p
	$M \pm SD$	$M \pm SD$	$M \pm SD$		
Decision conflict					
Total score	38.61 ± 13.47	38.44 ± 13.09	38.79 ± 13.88	0.04	.97
Subscale scores					
Uncertainty	45.05 ± 19.05	45.52 ± 19.31	44.57 ± 18.81	0.47	.64
Informed	39.74 ± 18.57	39.39 ± 18.69	40.11 ± 18.49	0.15	.89
Value clarity	37.29 ± 16.12	36.99 ± 16.10	37.59 ± 16.19	0.13	.90
Support	37.17 ± 15.98	37.26 ± 15.73	37.07 ± 16.28	0.78	.78
Effective decision	33.80 ± 14.77	33.03 ± 13.92	34.59 ± 15.59	0.78	.43
Psychological distress					
Intrusion subscale	15.24 ± 9.56	16.09 ± 10.25	14.37 ± 8.73	1.94	**.05**
	%	%	%	Wald	p
Clinically significant levels of distress (scores ≥20)[a]	34.0[a]	38.6[a]	29.3[a]	3.89[a]	**.05**[a]

Note. Higher scores indicate higher levels of decisional conflict. *IES* Impact of Events Scale.
[a] Based on validated case rule of IES scores ≥20 indicating clinically significant or elevated levels of distress.
[b] Participants with missing data on ethnicity and income variables were excluded from these analyses.
the bold values indicate statistical significance, p < .05

follow-up than those in the control group, B = 1.88, 95% CI [–0.03, 3.80], $t(383)$ = 1.94, p = .05. Additionally, more patients in the intervention group, compared with patients in the control group, met criteria for clinically significant psychological distress, 38.6% vs. 29.3%, respectively, B = –0.77, OR = 1.54, p = .05 (see Table 2).

As-treated analyses: comparing *Healing Choices* users and nonusers

Of the patients randomized to the *Healing Choices* intervention group, we had data on 232 participants indicating their user/nonuser status. Of the 232, 128 patients were identified as users and 104 as nonusers. As such, engagement with the tool within the intervention group was low—41.2%—and this prompted us to compare the software users and nonusers among the intervention group.

We compared users and nonusers on baseline demographics and clinical characteristics (see Table 3). The majority of the sample was White (85.8%) and had medical insurance (94.0%). There were no significant differences between users and nonusers with regard to baseline demographic, clinical, or psychological variables.

Within the *Healing Choices* group, analyses compared users of *Healing Choices* to nonusers of *Healing Choices* on measures of decisional conflict variables and psychological distress, assessed at the 2-month post-intervention point (see Table 4). Results of regression analyses (users vs. nonusers) indicated no statistically significant differences in the DCS total score, B = –2.29 (s.e. = 1.76), p = ns, or most of the subscales (uncertainty, B = –3.10 [s.e. = 2.60], p = ns; informed, B = –1.80 [s.e. = 2.39], p = ns; value clarity, B = 0.68 [s.e. = 2.18], p = ns; and effective decision, B = –3.50 [s.e. = 1.80], p = ns). However, there was a statistically significant difference in decisional support indicating that program users felt more supported than nonusers, B = –4.31 (s.e. = 2.09), p = .04. Further, there was no difference between program users and nonusers in psychological distress at follow-up, B = –2.51 (s.e. = 1.32), p = ns.

Participants' perception of Healing Choices

Several quantitative questions focused on assessing participants' perception of *Healing Choices*. Results showed that, of all website users, the majority "strongly agreed" or "agreed" with the following statements: the website increased my knowledge about breast cancer and its treatment (85.8%), helped me talk to my doctors about my breast cancer treatment (68.5%), helped me with my emotional concerns about breast cancer (76.4%), made me feel less anxious or upset about my breast cancer (68.5%), made me feel more confident in how I deal with my breast cancer (80.3%), helped me make treatment decisions (65.4%), and provided information that helped me deal with my breast cancer treatment (77.2%).

DISCUSSION

Our findings highlight several important areas for discussion. First, due to uncertainty about the level of usage in our intervention group (41%), we conducted both intent-to-treat and as-treated analyses. There is a debate in the literature on whether it is advisable to deviate from an intention-to-treat approach if there are protocol violations that limit the exposure to the intervention condition. Based mainly on their experience with pharmaceutical studies, Ranganathan et al. [24] recommend presenting both sets of results so readers can interpret the effect of the intervention fully, with an emphasis on the intent-to-treat analyses, which is the approach we used here.

Following the intention-to-treat protocol, we found that patients in the *Healing Choices* intervention did not report a benefit in reducing decisional conflict but displayed higher cancer-related psychological distress than patients in the comparison condition at 2-month post-intervention. Because

Table 3 | Baseline demographics and clinical characteristics comparing, within the intervention group, tool users vs. nonusers

	Intervention group with tool user status available (*N* = 232)	Users (*n* = 128)	Nonusers (*n* = 104)	*t* or χ^2	*p*
	M ± *SD* or %	*M* ± *SD* or %	*M* ± *SD* or %		
Age	56.21 ± 9.87	56.83 ± 9.40	55.44 ± 10.41	1.06	.29
Educational level					
High school graduate or less	21.6 %	21.9%	21.2%	0.78	.68
Some college	23.3%	21.1%	26.0%		
College graduate or more	55.2%	57.0%	52.9%		
Ethnicity					
Other	5.2%	4.7%	5.8%	1.63	.44
African-American	9.1%	7.0%	11.5%		
White	85.8%	88.3%	82.7%		
Income					
<$30,000	30.6%	28.1%	33.7%	4.54	.34
$30,000–$59,000	19.4%	16.4%	23.1%		
$60,000–$79,000	10.3%	11.7%	8.7%		
$80,000 or higher	32.8%	37.5%	26.9%		
BMI	28.13 ± 6.51	27.66 ± 6.39	28.70 ± 6.64	1.19	.23
Comorbidity	2.45 ± 2.18	2.13 ± 1.77	2.85 ± 2.55	1.81	.07
Medical insurance	94.0%	94.7%	93.3%	0.25	.75
Baseline psychological distress					
Intrusion subscale (IESI_BASELINE)	18.55 ± 8.45	17.61 ± 8.52	19.71 ± 8.25	1.88	.06
Clinically significant levels of distress (scores ≥20)[a]	45.0%[a]	42.1%[a]	48.5%[a]	0.96[a]	.33[a]

BMI body mass index; *IES* Impact of Events Scale.
[a] Based on validated case rule of IES scores ≥20 indicating clinically significant or elevated levels of distress.

Table 4 | Means and standard deviations for study outcomes at 2-month post-intervention, within the intervention group, tool users vs. nonusers

	Intervention group with tool user status available (*N* = 232)	Users (*n* = 128)	Nonusers (*n* = 104)	*t*	*p*
	M ± *SD*	*M* ± *SD*	*M* ± *SD*		
Decision conflict					
Total score	38.34 ± 12.91	37.33 ± 12.36	39.63 ± 13.54	1.30	.19
Subscale scores					
Uncertainty	45.94 ± 19.57	44.55 ± 19.43	47.65 ± 19.71	1.19	.24
Informed	39.27 ± 17.93	38.47 ± 17.45	40.26 ± 18.55	0.75	.45
Value clarity	37.72 ± 16.36	38.03 ± 16.70	37.35 ± 16.02	0.31	.76
Support	37.30 ± 15.83	35.36 ± 15.50	39.67 ± 15.99	2.06	**.04**
Effective decision	33.63 ± 13.62	32.07 ± 12.62	35.58 ± 14.61	1.90	.06
Psychological distress					
Intrusion subscale	15.96 ± 9.96	14.85 ± 9.82	17.36 ± 10.01	1.90	.06
	%	%	%	Wald	*p*
Clinically significant levels of distress (scores ≥20)[a]	37.9%[a]	34.1%[a]	42.6%[a]	1.70[a]	.19[a]

Note. Higher scores indicate higher levels of decisional conflict. *IES* Impact of Events Scale.
[a] Based on validated case rule of IES scores ≥20 indicating clinically significant or elevated levels of distress.
the bold values indicate statistical significance, p < .05

59% of patients assigned to the intervention condition did not use the *Healing Choices* program, we examined decisional conflict and distress levels among those patients who actually used the program in an as-treated analysis. This analysis showed that the intervention provided benefit in terms of decisional support, but also that there was no significant difference in cancer-related psychological distress between users and nonusers of the program. Thus, using the *Healing*

Choices program facilitated decision-making but also did not cause increased distress.

One possible explanation for the unintended effect of the intervention found during intention-to-treat analyses might be related to the phenomenon of "information overload." On the one hand, informed decision-making is critically important and has been linked to various positive outcomes, including less decisional regret [25]. On the other hand, "information overload" occurs when decision-makers face a level of information that is greater than their information processing capacity [26, 27]. "Information overload" has been associated with cancer information avoidance [28] and has been identified as a barrier to comprehension of somatic tumor screening test results in a qualitative study of patients with advanced cancer. It is possible that having access to *Healing Choices* emphasized the complexity of information involved in decision-making, beyond the level that some patients could process. The *Healing Choices* library contained over 100 pages of text and graphics on breast cancer, plus it offered patient stories, physician expert information, and communication tips and treatment management tools. It is certainly possible that the amount and detail of information may have been perceived as overwhelming. For the nearly 60% of intervention participants who did not access *Healing Choices*, elevated stress may have been a barrier to engagement. Future research should aim to identify how much information patients with a particular demographic and clinical profile desire and can cope with, before implementing an information-based intervention.

Aside from unexpected findings related to psychological distress, the intent-to-treat analyses indicate that there were no significant differences in decisional conflict or any of the subscales between those assigned to *Healing Choices* versus the comparison condition. There are several possible explanations for the lack of significant findings on the decisional conflict measure. First, our study had a very strong usual care control condition. Participants were recruited for the RCT after making a phone call to a trained cancer information specialist to have a specific question answered or concern addressed. They were recruited into the study at the end of the phone call. Information specialists are trained in answering questions and provide referral to other information sources; thus, it is highly likely that the primary purpose of the call was addressed, reducing the need for further information. Second, it was not possible to document why participants made their original calls, and therefore, we do not know how many participants were calling for assistance with treatment decision-making for breast cancer.. It is entirely possible that gaining assistance with treatment decision-making (the primary focus of *Healing Choices*) was not a further concern for some of the enrolled patients. Third, to reduce patient burden, the research staff were only able to spend a short amount of time with participants at baseline and at follow-up assessments, leaving little time to explore decisional conflict beyond assessing this construct with a brief quantitative measure. Fourth, we relied on self-report to determine usage of *Healing Choices*, which may have been influenced by social desirability or recall bias. Our ongoing work in this area uses objective tracking software to determine software usage.

Engagement with *Healing Choices* was 41%, a lower rate than reported in the literature [29]. A possible explanation for our low engagement rate could be the procedures we used to recruit study participants. Patients called a cancer information specialist for answers to specific questions related to their cancer diagnosis or treatment. Their questions were answered during the telephone call and they were enrolled into our study at the end of this call. It is certainly possible that participants who already had their questions answered were less motivated to engage in the educational intervention program.

To increase initial patient engagement with electronic interventions may require considerable time, money, and resources, all of which need to be budgeted for. It may be important to ensure that the intervention modality matches the patients' preferences, comfort level, and specific needs. For example, some concerns, such as solving complicated issues of self-care, may benefit from demonstration. However, emotional concerns may require support through interaction, indicating the need for more intensive interventions, including access to more cost-effective web-based tools. Other challenges (e.g., presenting pros and cons, providing information) may be able to be addressed with paper pamphlets [30]. Although, as indicated in standard practice, we included patient stakeholders in the development of patient facing tools, it is clear that feedback from patient stakeholders is needed throughout the entire development process to not only increase participant consent rate but also increase participant engagement with the tools.

Based on as-treated analyses, we believe our program is not only valuable, but also unique compared with existing programs. First, our program is unique in that it was designed to be evaluated in conjunction with the procedures of the Cancer Information Service, a service provided by National Cancer Institute that provides accurate, up to date, easy to understand, and reliable information about cancer and its treatment. The service is free to use, confidential, and the information is administered by trained specialists. Second, at the time it was evaluated, our program was the first of its kind. Our group presented on these data nationally and we believe it served as a model for subsequent iterations of educational and decisional tools as well as preference elicitation approaches in web-based programs including those focusing on low health literate populations [31]. Formal publication of this work in the peer-reviewed literature is important to maximize its impact. Third, our program is unique because it is part of a comprehensive suite of web-based programs to provide information to not only breast cancer patients but also prostate cancer patients [32] and breast cancer survivors.

Limitations

There are several limitations to this work. First, although women who had already made a treatment decision were excluded from the study, women did not have to be experiencing decisional uncertainty or heightened distress to participate. Second, as referenced earlier, in order to minimize patient burden and keep the interviews brief, we did not assess other relevant factors such as information processing, comprehension skills, illness cognitions, preferred role in decision-making, and other sources of support, leading to a limited baseline interview. Our efforts to reduce participant burden also hindered us from collecting imperative information, such as baseline decisional conflict, engagement with the intervention at follow-up and potential barriers to engagement. Third, we did not collect data on process-level variables (e.g., improved patient–provider communication) that could have informed our understanding of decision

support needs and been instrumental in designing future interventions. Fourth, as referenced, our usage variable was binary and self-report, and thus we were unable to leverage the sophisticated tracking features that are available through objective measures of software usage. Fifth, as we did not collect treatment decision at the 2-month follow-up assessment, we could not conduct analyses to determine whether treatment decision impacted our outcomes of interest (decisional conflict and psychological distress). Sixth, we did not collect data on time since diagnosis, which tends to be correlated with distress and informational needs. Seventh, given that our sample is drawn from patients who initiated contact with an information center, it is likely that their experience and engagement rate will be different from those patients who are not naturally information-seeking. Future work should utilize a "prescriptive approach" in which use of the intervention could be prescribed by clinical providers, thus increasing the likelihood that patients, and particularly those who do not naturally seek information, will consistently use these programs. Eighth, even though the mode of intervention delivery (i.e., CD-ROM delivered via UPS) fell out of usage because of ubiquitous internet and text-message availability, our major findings, such as the relationship between information overload and increased psychological distress, are just as relevant today as they were during the conduct of the study. Lastly, our participant population was predominantly White and well educated, which could have impacted baseline knowledge.

CONCLUSIONS

Based on intent-to-treat analyses, we found no significant difference in decisional conflict, although psychological distress was higher in the *Healing Choices* intervention group than in the control group at 2-month post-study entry, potentially due to information overload. Low engagement with the intervention prompted as-treated analysis comparing program users and nonusers, which showed a positive impact of the intervention, that users reported increased decisional support. Future work should delineate the boundary between providing the right amount of information and "information overload," while tailoring and targeting information and providing strategies to overcome barriers to engagement (e.g., providing incentives to initially engage the program), thereby maximizing the efficacy of the intervention.

Funding

This research was funded by the National Cancer Institute under Grants No. NCI 2P01-CA057586, 1R01 CA158019-01, R21 CA176551, P30 CA 006927, and 5P01CA057586, and the American Cancer Society Research Scholar Grant No. RSG-15-021-01-CPPB.

Compliance with Ethical Standards

Conflict of Interest: All authors declare that they have no conflicts of interest.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This research was approved by the Institutional Review Boards (IRBs) of the University of Colorado Denver, Anschutz Medical Campus, as well as the collaborating research institutions (i.e., University of California, Los Angeles, and Fox Chase Cancer Center) and parent institutions of the three CIS contact centers (i.e., University of Miami, Fred Hutchinson Cancer Research Center, and Memorial Sloan Kettering Cancer Center).

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Welfare of Animals: This article does not contain any studies with animals performed by any of the authors.

Transparency Statement

1. This study was registered after the study began. This study is registered on clinicaltrials.gov at: https://clinicaltrials.gov/ct2/show/NCT00830635.

2. The analysis plan was not formally preregistered.

3. Deidentified data from this study are not available in a public archive. Deidentified data from this study will be made available (as allowable according to institutional IRB standards) by emailing the corresponding author.

4. Analytic code used to conduct the analyses presented in this study is not available in a public archive. They may be available by emailing the corresponding author.

5. Materials used to conduct the study are not publicly available.

REFERENCES

1. American Cancer Society. *Breast Cancer Facts & Figures 2019–2020.* 2019.
2. Gornick MC, Zikmund-Fisher BJ. What clinical ethics can learn from decision science. *AMA J Ethics.* 2019;21(10):E906–E912.
3. Witteman HO, Scherer LD, Gavaruzzi T, et al. Design features of explicit values clarification methods: a systematic review. *Med Decis Making.* 2016;36(4):453–471.
4. Witteman HO, Julien A-S, Ndjaboue R, et al. What helps people make values-congruent medical decisions? Eleven strategies tested across 6 studies. *Med Decis Making.* 2020;40(3):266–278.
5. Diefenbach MA, Dorsey J, Uzzo RG, et al. Decision-making strategies for patients with localized prostate cancer. *Semin Urol Oncol.* 2002;20(1):55–62.
6. Orom H, Penner LA, West BT, Downs TM, Rayford W, Underwood W. Personality predicts prostate cancer treatment decision-making difficulty and satisfaction. *Psychooncology.* 2009;18(3):290–299.
7. Orom H, Underwood W, Biddle C. Emotional distress increases the likelihood of undergoing surgery among men with localized prostate cancer. *J Urol.* 2017;197(2):350–355.
8. Diefenbach MA, Butz BP. A multimedia interactive education system for prostate cancer patients: development and preliminary evaluation. *J Med Internet Res.* 2004;6(1):e3.
9. Diefenbach MA, Mohamed NE, Butz BP, et al. Acceptability and preliminary feasibility of an internet/CD-ROM-based education and decision program for early-stage prostate cancer patients: randomized pilot study. *J Med Internet Res.* 2012;14(1):e6.
10. Salonen A, Ryhänen AM, Leino-Kilpi H. Educational benefits of Internet and computer-based programmes for prostate cancer patients: a systematic review. *Patient Educ Couns.* 2014;94(1):10–19.
11. McDermott MS, While AE. Maximizing the healthcare environment: a systematic review exploring the potential of computer technology to promote self-management of chronic illness in healthcare settings. *Patient Educ Couns.* 2013;92(1):13–22.

12. Bandura A. Human agency in social cognitive theory. *Am Psychol*. 1989;44(9):1175–1184.
13. Janz NK, Becker MH. The Health Belief Model: a decade later. *Health Educ Q*. 1984;11(1):1–47.
14. Usher-Smith JA, Winther LR, Shefer GS, Silarova B, Payne RA, Griffin SJ. Factors associated with engagement with a web-based lifestyle intervention following provision of coronary heart disease risk: mixed methods study. *J Med Internet Res*. 2017;19(10):e351.
15. Guertler D, Vandelanotte C, Kirwan M, Duncan MJ. Engagement and nonusage attrition with a free physical activity promotion program: the case of 10,000 steps Australia. *J Med Internet Res*. 2015;17(7):e176.
16. Marcus AC, Diefenbach MA, Stanton AL, et al.; CISRC Research Team. Cancer patient and survivor research from the Cancer Information Service Research Consortium: a preview of three large randomized trials and initial lessons learned. *J Health Commun*. 2013;18(5):543–562.
17. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis*. 1987;40(5):373–383.
18. Horowitz M, Wilner N, Alvarez W. Impact of Event Scale: a measure of subjective stress. *Psychosom Med*. 1979;41(3):209–218.
19. Hutchings E, Devilly GJ. Impact of Events Scale. Secondary Impact of Events Scale. Available at https://www.clintools.com/victims/resources/assessment/ptsd/ies.html (accessed June 21, 2023).
20. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15(1):25–30.
21. IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.
22. SAS. Statistical Analysis Software. Users' Guide Statistics Version 9.4. 2013. SAS Institute Inc., Cary.
23. Wenzel LB, Fairclough DL, Brady MJ, et al. Age-related differences in the quality of life of breast carcinoma patients after treatment. *Cancer*. 1999;86(9):1768–1774.
24. Ranganathan P, Pramesh CS, Aggarwal R. Common pitfalls in statistical analysis: intention-to-treat versus per-protocol analysis. *Perspect Clin Res*. 2016;7(3):144–146.
25. Hoffman RM, Lo M, Clark JA, et al. Treatment decision regret among long-term survivors of localized prostate cancer: results from the Prostate Cancer Outcomes Study. *J Clin Oncol*. 2017;35(20):2306–2314.
26. Schroder HM, Driver MJ, Streufert S. *Human Information Processing: Individuals and Groups Functioning in Complex Social Situations*. New York: Holt, Rinehart and Winston; 1967.
27. Eppler M, Mengis J. The concept of information overload: a review of literature from organization science, accounting, marketing, MIS, and related disciplines. *Inf Soc*. 2004;20(5):325–344.
28. Chae J. Who avoids cancer information? Examining a psychological process leading to cancer information avoidance. *J Health Commun*. 2016;21(7):837–844.
29. Gottvall M, Fagerkvist K, Lampic C, Wettergren L. Including a discussion forum in a web-based intervention on fertility and sexuality following cancer—usage and content. *Internet Interv*. 2022;8(29):100559.
30. Mistretta T DM, Diefenbach MA, Marziliano A, Yacoub A. Informed/shared decision making for prostate cancer screening among members of the World Trade Center Health Program [online poster presentation]. SMDM 43rd Annual Meeting; 2021.
31. Diefenbach M, Pfister H, Tagai EK, et al. *Preference Elicitation and Treatment Decision Making among Men Diagnosed with Localized Prostate Cancer: Results from the Healium Trial*. Baltimore, MD: Society of Behavioral Medicine; 2022.
32. Diefenbach M, Benedict C, Miller SM, et al. Examining the impact of a multimedia intervention on treatment decision-making among newly diagnosed prostate cancer patients: results from a nationwide RCT. *Transl Behav Med*. 2018;8(6):876–886.