

Project Connect Online: Randomized Trial of an Internet-Based Program to Chronicle the Cancer Experience and Facilitate Communication

Annette L. Stanton, Elizabeth H. Thompson, Catherine M. Crespi, John S. Link, and James R. Waisman

Annette L. Stanton, Elizabeth H. Thompson, Catherine M. Crespi, University of California at Los Angeles, Los Angeles; John S. Link, Breastlink Medical Group, Orange; and James R. Waisman, City of Hope, Duarte, CA.

Published online ahead of print at www.jco.org on August 12, 2013.

Supported by funding from Breast Cancer Research Foundation, Susan G. Komen for the Cure Foundation (Grant No. BCTR0707901 to A.L.S.), and National Institutes of Health (Grant No. CA016042 to C.M.C.).

Presented in part at the Annual Meeting of the American Psychosomatic Society, March 9-12, 2011, San Antonio, TX, and the Annual Meeting of the Society of Behavioral Medicine, April 27-30, 2011, Washington, DC.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

Corresponding author: Annette L. Stanton, PhD, Department of Psychology, 1285 Franz Hall, Box 951563, UCLA, Los Angeles, CA 90095-1563; e-mail: astanton@ucla.edu.

© 2013 by American Society of Clinical Oncology

0732-183X/13/3127w-3411w/\$20.00

DOI: 10.1200/JCO.2012.46.9015

ABSTRACT

Purpose

Evidence suggests that expressing emotions related to cancer and receiving interpersonal support can promote psychological and physical health in women diagnosed with breast cancer. However, adaptive expression of feelings and communication with one's social network can pose challenges for patients with cancer. We report on a randomized controlled trial of an intervention, Project Connect Online, for patients with breast cancer to create personal Web sites to chronicle their experience and communicate with their social network.

Patients and Methods

Women (N = 88) diagnosed with breast cancer (any stage, any interval since diagnosis) were randomly assigned to participate in a 3-hour workshop for hands-on creation of personal Web sites with a follow-up call to facilitate Web site use, or to a waiting-list control. Assessed before randomization and 6 months after the intervention, dependent variables included depressive symptoms, positive and negative mood, cancer-related intrusive thoughts, and perceived cancer-related benefits in life appreciation and strengthened relationships.

Results

Relative to control participants, women randomly assigned to Project Connect Online evidenced significant benefit 6 months later on depressive symptoms, positive mood, and life appreciation, but not negative mood, perceived strengthened relationships, or intrusive thoughts. Treatment status moderated the intervention effects, such that women currently undergoing medical treatment for cancer benefitted significantly more from the intervention on depressive symptoms and positive mood than did women not receiving treatment.

Conclusion

Findings suggest the promise of an intervention to facilitate the ability of women diagnosed with breast cancer to chronicle their experience and communicate with their social network via the Internet.

J Clin Oncol 31:3411-3417. © 2013 by American Society of Clinical Oncology

INTRODUCTION

Most commonly, breast cancer is not experienced in isolation, but rather within an interpersonal nexus. Supportive relationships can serve as crucial resources during the cancer experience, whereas social constraint and isolation bode ill for psychological and physical health (eg,¹⁻⁷). Communication can pose challenges, however, both for the cancer survivor and supportive others. The woman may want to keep others apprised of her status, but may lack the energy, fear becoming a burden, or anticipate unhelpful reactions. Friends and family may want to gain information and provide support, but might not know what to ask or how to offer effective support. Providing a channel for communication might

not only facilitate interpersonal support, but also present a vehicle for expressing emotions and bolstering a sense of self-efficacy, factors that can promote adjustment.^{8,9} Our aim was to develop and test in a randomized controlled trial an Internet-based platform, Project Connect Online (PCO), for chronicling the experience and promoting communication by women with cancer.

Most psychosocial interventions that include an interpersonal component have been directed toward enhancing the patient-caregiver relationship or fostering relationships with other patients with cancer (eg,^{10,11}). Promoting communication within the broader interpersonal circle also might carry benefit. Some evidence demonstrates that patients with breast cancer receive more support from

friends than from male partners,¹² and friends/family can offset the negative effects of partners' unsupportive behaviors.⁵ Peer discussion groups are particularly effective for women with unsupportive partners.¹⁰ Family and friends also desire information and support.¹³ Such findings suggest that interventions to enhance communication within the interpersonal network could promote well-being for both the survivor and others.

Personal Web sites are of interest to cancer survivors, as evidenced by several such platforms.^{14,15} A qualitative study of 50 personal Web sites of patients with breast cancer¹⁶ demonstrated that they frequently provided detailed accounts of women's experiences, provided a way to connect with others, and offered help to other patients with cancer. The researchers¹⁶ suggested that the Web sites offered a vehicle for expressing emotion and bolstering a sense of efficacy/control. Whether such Web sites are effective in bolstering psychological and physical health-related adjustment of cancer survivors is unknown, however.

To our knowledge, ours is the first research to evaluate an intervention to teach patients with cancer personal Web site development. The primary hypothesis was that, relative to women assigned to a waiting-list control condition, women trained to create a personal Web site would improve in general psychological adjustment (depressive symptoms, negative/positive mood) and cancer-specific adjustment (cancer-related intrusive feelings/thoughts, perceived cancer-related benefits of strengthened relationships and life appreciation) 6 months later. With the rationale that women undergoing

medical treatment would have a greater need to manage communication and express emotions than women who had completed treatment, we also hypothesized that PCO would be more effective for the former.

PATIENTS AND METHODS

Patients

Participants were recruited from a community medical oncology practice specializing in breast cancer. Eligibility criteria included the following: age at least 18 years; diagnosis of invasive or metastatic breast cancer (any interval since diagnosis); ability to complete the intervention and questionnaires in English; no existing personal Web site (any comfort/skill level with computers allowed). Participants also had to return the baseline questionnaire within 1 month of receipt. This preliminary trial was designed to establish whether effect sizes were sufficient to pursue a larger trial and to detect large effects ($d = 0.80$) in an analysis of covariance with 80% power, two-sided $P < .05$, and 20% attrition, which required 33 participants per group. Sample size was expanded to 44 per group because of available resources.

Of 440 women approached, 8% ($n = 37$) were ineligible, 72% ($n = 315$) declined to hear more about the study or were unreachable by telephone, and 20% ($n = 88$) were randomly assigned and included in analyses (Fig 1). Of the 88 women randomly assigned, 86% ($n = 76$) completed the 1-month assessment, and 86% ($n = 76$) completed the 6-month assessment.

Procedure

On institutional review board approval, within clinic scheduling constraints, consecutive potentially eligible patients were approached at a medical

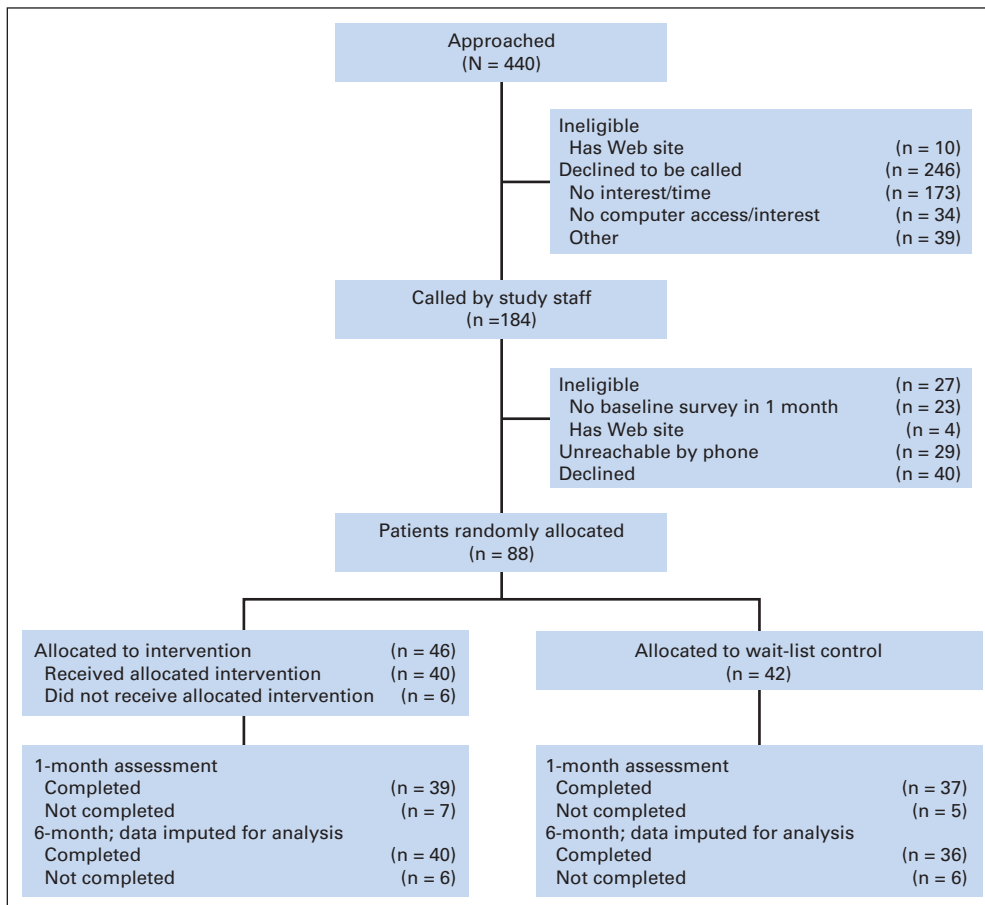


Fig 1. Project Connect Online accrual and retention.

appointment by the clinic's research coordinator, following a standard verbal script. Women were informed that the purpose of the research was "to evaluate a workshop held here to create your own personal Web site to communicate with friends and loved ones about your experience." Treating physicians were unaware of patients' participation.

With verbal consent, the research coordinator provided contact information to research staff, who called potentially eligible women to describe the study and confirm eligibility. Interested and eligible women were mailed informed consent forms and questionnaires, which they returned by mail. After packet return, each participant's assigned condition was revealed to research staff from a random allocation sequence generated by a biostatistician uninvolved in the trial, whereupon staff called to schedule the intervention session or inform the participant that she would continue assessments and be offered the workshop in 6 months. One and 6 months after the intervention, women completed and returned additional questionnaires by mail. Timing of assessments was designed to capture change in potential mediators at 1 month (not reported here) and mediators and effects of PCO after sufficient time to use the Web site (6 months). Data entry personnel were unaware of participants' condition assignment. Participants were compensated \$50 per returned questionnaire.

PCO intervention. Three phases informed the development of PCO: semistructured interviews of eight patients with breast cancer who had created cancer-related personal Web sites; focus groups of seven patients with breast cancer to evaluate barriers, facilitators, and preferences for creating Web sites (Appendix, online only); and, once the Web site template, manual, and workshop protocol were developed, a pilot intervention session with four patients with breast cancer to elicit feedback, with resulting slight modifications before launching PCO.

The researchers collaborated with a Web site development firm,¹⁷ using the WordPress multisite Web site and blogging platform,¹⁸ to develop a design that allowed for personalization of esthetics and content (eg, Web site template, links). Each template contained six identical functions (1): a journal (blog) that could contain photos; (2) a section for Web site links, to be populated by each participant (a list of potential Web sites was provided by the researchers [eg, the oncology clinic, National Cancer Institute, American Society of Clinical Oncology public site]); (3) a How You Can Help page, in which participants could convey actions visitors could undertake (eg, meal provision, written cards); (4) choice of privacy settings; (5) instructions for visitors to post messages and subscribe for automatic notification of Web site updates; and (6) an online survey to assess visitors' reactions to PCO (data not reported here). The researchers and Web site development firm also created a 48-page manual with written and visual instructions for Web site creation and maintenance and online step-by-step video tutorials for creating/maintaining Web site functions (eg, adding a link or photo).

Once a minimum of three women were randomly assigned to the intervention, two members of the research team (A.L.S., E.H.T., postbaccalaureate research staff) conducted a 3-hour intervention session in a conference room of the medical oncology practice. Participants could use a researcher-provided laptop computer or bring their own. Delivered in groups of one to five participants (along with significant others), the intervention, accompanied by the take-home manual, involved (1) a description of potential functions of personal Web sites (eg, keep others informed, manage communication, chronicle the experience); (2) proactive discussion of common concerns about maintaining a Web site (eg, perceived pressure to post frequent updates or to convey only positive content; see Appendix); (3) demonstration of all Web site functions (ie, privacy settings, journal, photo posting, links, How You Can Help page, visitor survey); (4) discussion of how to introduce the Web site to others; (5) demonstration of online tutorials; and (6) hands-on creation of the Web site, which involved selecting one of 11 templates, creating a Web site title, and initiating the first journal post to introduce others to the Web site. A toll-free phone number was provided for technical support from the Web site development firm. As scheduled during the intervention session, a researcher (E.H.T.) called each participant 1 week later to respond to questions. Conversations were less than 15 minutes. Wireless access was available during oncology clinic hours for participants to update Web sites, and cameras and laptops were available for check-out.

Waiting-list control. Patients in the control condition completed the baseline and follow-up assessments and otherwise received standard medical care. Participation in PCO was offered once women had completed the 6-month assessment; eight patients participated.

Measures

At baseline, participants self-reported sociodemographic (ie, age, education, race/ethnicity, employment, partner status, familial/social network data) and cancer-related variables (ie, diagnosis date, stage, treatment status, specific treatments).

Outcomes were measured at each assessment. Depressive symptoms were assessed using the Center for Epidemiologic Studies Depression Scale.¹⁹ Internal consistency reliability was high at all assessments ($\alpha = 0.89$ to 0.91). Participants completed the Profile of Mood States²⁰ with regard to their feelings in the past week. As in other studies with samples of patients with cancer,²¹⁻²⁵ we constructed a negative mood index from items (eg, sad, tense) on the highly correlated anger, depression, tension, fatigue, and confusion subscales and a positive mood index with the vigor subscale items (eg, cheerful, lively). Internal consistency reliabilities were high for negative ($\alpha = 0.96$ to 0.97) and positive ($\alpha = 0.79$ to 0.93) mood. Within assessment points, correlations between these dependent variables ranged in absolute value from $r = 0.48$ to 0.79 , all $P < .01$.

Participants also completed cancer-related outcome measures. On the 7-item Impact of Event–Intrusion subscale,²⁶ which assesses cancer-related intrusive thoughts and feelings, women rated how frequently each item (eg, "I had waves of strong feelings about it") was true for them during the past 7 days with regard to their cancer experience ($\alpha = 0.87$ to 0.89). With the rationale that PCO could bolster perceived cancer-related benefits in specific domains, Posttraumatic Growth Inventory (PTGI)²⁷ subscales selected for assessment were Appreciation of Life (eg, "I can better appreciate each day"; $\alpha = 0.83$ to 0.83) and Relating to Others (eg, "I more clearly see that I can count on people in times of trouble"; $\alpha = 0.87$ to 0.89). Women rated items for the degree to which each change had occurred as a result of the cancer experience. Within assessment points, correlations of PTGI subscales with Impact of Event–Intrusion ranged from $r = -0.02$ to 0.14 , all $P > .10$.

Fidelity to the PCO workshop protocol (ie, evidence that the intervention was delivered as intended) was assessed on a 20-item author-constructed measure by two research staff uninvolved in PCO performance. With informed consent, intervention sessions were audio recorded. Each yes/no item (eg, "discussed common concerns about using a Web site and how these can be proactively addressed," "explained privacy settings and demonstrated how to change them") was rated independently by raters while listening to each tape.

Data Analysis

All analyses were preplanned. The randomized groups were compared on all baseline variables using χ^2 for categorical variables and t tests for continuous variables. Treatment fidelity was calculated as the percentage of workshop protocol elements covered, as judged by two independent raters. Outcome analyses were conducted using analysis of covariance, with the 6-month measure as the dependent variable and group assignment, current medical treatment (radiotherapy, chemotherapy, biologic therapy [endocrine therapy not counted]: yes/no), their interaction, and the baseline measure as independent variables. No adjustment was made to correct for multiple statistical comparisons. Main effects were estimated as adjusted mean differences between levels of each factor. When the interaction was significant, we estimated differences in adjusted means among pairs of the four cells defined by the interaction. Intent-to-treat analyses were conducted using Markov chain Monte Carlo multiple imputation²⁸⁻³⁰ of missing outcomes under a missing at random assumption, as implemented in SAS PROC MI; 30 imputed data sets were analyzed and estimates combined using PROC MI ANALYZE (see Appendix for details). Analyses were repeated with data of participants retained at 6 months. Cohen d effect sizes were obtained as differences in adjusted means using standardized variables in analyses. Analyses were conducted using SAS version 9.3 (SAS Institute, Cary, NC).

RESULTS

Sample Characteristics

Most participants were married, non-Hispanic white, college graduates, and employed outside the home (Table 1). On average, participants were 56 years old and had been diagnosed with breast cancer more than 5 years earlier. Twenty-one women were in medical treatment, and 17 had metastatic disease.

The randomized groups did not differ significantly (all $P > .05$) at baseline on any demographic, cancer-related, or outcome measure, nor was treatment status or the interaction of condition with treatment status associated with significant differences on any baseline variable. Although not statistically significant, women in current medical treatment had somewhat worse status on all outcomes at baseline. Baseline variables did not differ significantly at $P < .05$ between participants who completed ($n = 76$) or did not complete ($n = 12$) the 6-month assessment.

Treatment Fidelity

Eight of 15 sessions were audio taped in full. On the measure of treatment fidelity, two independent raters agreed that there was 100% fidelity to the workshop protocol.

Outcome Analyses

General measures of psychological adjustment. Intent-to-treat results for depressive symptoms and negative and positive mood are presented in Table 2, with additional results pertinent to the significant interactions displayed in Table 3. All effect sizes for statistically significant effects were moderate to large. Women in medical treatment reported more depressive symptoms at 6 months than did those not in treatment ($P = .04$), and PCO produced a significant benefit on depressive symptoms ($P = .009$). These main effects were qualified by a significant interaction ($P = .03$; Fig 2), whereby PCO buffered the increase in depressive symptoms experienced by women in medical treatment who were assigned to the control condition. Specifically, for PCO participants, 6-month depressive symptoms did not differ significantly as a function of medical treatment, and they were significantly lower than depressive symptoms of control patients in medical treatment (all $P < .006$). Control participants in medical treatment demonstrated a significant increase in depressive symptoms compared with women not in treatment ($P = .004$). Effects on negative mood were not statistically significant, although the pattern of cell means mirrored that for depressive symptoms.

PCO produced a significant improvement in positive mood ($P = .03$), which was qualified by a significant interaction ($P = .04$; Fig 2). Again, the intervention buffered the effect of being in medical treatment on positive mood. Control participants receiving medical treatment declined in positive mood over time, relative to improved positive mood in the other three groups (all $P < .05$), which did not differ from each other.

When analyses were repeated on data from the 75 participants retained at 6 months, all statistically significant effects remained (see Appendix). In addition, PCO had a significant effect on negative mood ($P = .02$) qualified by a significant interaction ($P = .03$), with the pattern of results mirroring that for depressive symptoms.

Cancer-related psychological adjustment. In intent-to-treat analyses, PCO produced a significant effect on deepened life appreciation

Table 1. Characteristics of Participants at Baseline (N = 88)

Characteristic	Control Group Participants (n = 42)		Project Connect Online Participants (n = 46)	
	No.	%	No.	%
Age, years				
Mean	56		55	
SD	10		12	
Range	37-76		28-76	
Race				
Non-Hispanic white	33	83	39	87
African American	2	5	1	2
Asian American	4	10	0	0
Latina	0	0	5	11
American Indian	1	3	0	0
College graduate	30	71	29	63
Employed \geq 30 h per week outside home	24	57	21	46
Married/living as married	25	60	34	74
Time since first breast cancer diagnosis, years				
< 2	14	33	7	15
2-5	9	21	18	39
5-10	14	33	16	35
\geq 10	5	12	5	11
Metastatic breast cancer diagnosis	8	22	9	21
Current primary medical treatment	11	26	10	22
Dependent variables at baseline				
CES-D				
Mean	12		11	
SD	10		9	
Range	0-36		0-34	
POMS-Negative Mood				
Mean	35		30	
SD	34		27	
Range	-7-119		-4-92	
POMS-Vigor				
Mean	18		16	
SD	6		8	
Range	5-30		0-32	
Impact of Event Scale (Intrusion)				
Mean	11		8	
SD	9		7	
Range	0-35		0-25	
PTGI Relating to Others Subscale				
Mean	24		22	
SD	7		8	
Range	6-34		3-35	
PTGI Life Appreciation Subscale				
Mean	11		11	
SD	3		3	
Range	3-15		3-15	

Abbreviations: CES-D, Center for Epidemiologic Studies Depression Scale; POMS, Profile of Mood States; PTGI, Posttraumatic Growth Inventory; SD, standard deviation.

relative to the control condition ($P = .03$). The interaction was not statistically significant ($P = .09$), although the means conformed to the same pattern as that for the general adjustment measures. No significant main or interaction effects emerged on cancer-related intrusion or on perceived strengthened relationships.

Table 2. Results of Intent-to-Treat Outcome Analysis for Project Connect Online (N = 88)

Outcome	Main Effect of Group Assignment							Main Effect of Medical Treatment Status							Interaction, <i>P</i>
	PCO (n = 46)		Control (n = 42)		<i>P</i>	Cohen <i>d</i>	95% CI	Current Treatment (n = 21)		Not in Treatment (n = 67)		<i>P</i>	Cohen <i>d</i>	95% CI	
	Adjusted Mean	SE	Adjusted Mean	SE				Adjusted Mean	SE	Adjusted Mean	SE				
CES-D	9.7	1.6	15.5	1.7	.009	0.6	0.1 to 1.1	15.7	1.7	10.1	1.0	.04	0.6	0.0 to 1.1	.03
POMS-Negative Mood	22.4	3.8	30.1	3.8	.14	0.3	-0.1 to 0.7	29.5	4.7	22.9	2.6	.20	0.3	-0.2 to 0.8	.16
POMS-Vigor	18.2	1.2	14.7	1.2	.03	0.5	0.1 to 0.9	15.4	1.5	17.4	0.8	.42	0.2	-0.3 to 0.7	.04
Impact of Event Scale (Intrusion)	8.5	1.0	11.6	1.0	.13	0.4	-0.1 to 0.8	11.7	1.3	8.5	0.7	.12	0.4	-0.1 to 0.8	.89
PTGI Relating to Others Subscale	23.0	1.1	23.2	1.1	.45	0.2	-0.3 to 0.6	22.9	1.4	23.3	0.8	.41	0.2	-0.3 to 0.7	.37
PTGI Life Appreciation Subscale	9.8	0.5	8.7	0.5	.03	0.5	0.1 to 0.9	8.3	0.6	10.2	0.3	.15	0.3	-0.1 to 0.7	.09

NOTE. Estimates are from general linear models with measurement at 6-month assessment as dependent variable and baseline measurement, group assignment, current medical treatment status, and the interaction between group assignment and current treatment status as independent variables. Means are adjusted for other effects in the model by holding such effects constant at their marginal means. Cohen *d* effect sizes provide the effects on a pooled standard deviation scale. Results are based on 30 multiply imputed data sets.

Abbreviations: CES-D, Center for Epidemiologic Studies Depression Scale; PCO, Project Connect Online; POMS, Profile of Mood States; PTGI, Posttraumatic Growth Inventory.

When analyses were repeated for participants retained at 6 months, the significant effect on PTGI life appreciation remained ($P = .002$), and the interaction was statistically significant ($P = .03$). Again, control participants who were receiving medical treatment had significantly lower life appreciation at 6 months compared with the other three groups (all $P < .004$). In addition, PCO had a marginally significant effect on cancer-related intrusive thoughts and feelings

($P = .06$), with a decline in cancer-related intrusions in PCO compared with the control condition.

DISCUSSION

PCO demonstrated positive, statistically significant effects on depressive symptoms, positive mood, and life appreciation. These effects are

Table 3. Effect Sizes for Outcomes With Significant Interaction Effects, Intent-to-Treat Analysis (N = 88)

Outcome	Cohen <i>d</i> Effect Sizes, Differences in Adjusted Cell Means									
	Adjusted Cell Mean				PCO v Control for Participants in Treatment (A v B)	PCO v Control for Participants Not in Treatment (C v D)	Current Treatment v Not in Treatment for Control Group Assignees (B v D)	Current Treatment v Not in Treatment for PCO Group Assignees (A v C)	PCO Assignees in Treatment v Control Assignees Not in Treatment (A v D)	Control Assignees in Treatment v PCO Assignees Not in Treatment (B v C)
	A. PCO and Current Medical Treatment (n = 10)	B. Control and Current Medical Treatment (n = 11)	C. PCO and Not in Medical Treatment (n = 36)	D. Control and Not in Medical Treatment (n = 31)						
CES-D										
Mean	10.1	20.6	9.4	10.4	1.1	0.1	1.1	0.1	0.0	1.2
SE	2.9	3.1	1.5	1.6						
95% CI					0.3 to 1.9	-0.3 to 0.5	0.3 to 1.8	-0.6 to 0.7	-0.7 to 0.7	0.5 to 1.9
<i>P</i>					.006	.64	.004	.84	.91	.001
POMS-Vigor										
Mean	20.1	11.6	18.0	17.4	0.9	0.1	0.6	0.2	0.3	0.7
SE	2.8	2.6	1.3	1.5						
95% CI					0.2 to 1.7	-0.4 to 0.5	0.0 to 1.3	-0.5 to 0.9	-0.4 to 1.0	0.1 to 1.3
<i>P</i>					.02	.78	.05	.52	.43	.03

NOTE. Estimates are from general linear models with measurement at 6-month assessment as dependent variable and baseline measurement, group assignment, current medical treatment status, and the interaction between group assignment and current treatment status as independent variables. Means are adjusted for other effects in the model by holding such effects constant at their marginal means. Cohen *d* effect sizes provide the effects on a pooled standard deviation scale. Results are based on 30 multiply imputed data sets.

Abbreviations: CES-D, Center for Epidemiologic Studies Depression Scale; PCO, Project Connect Online; POMS, Profile of Mood States.

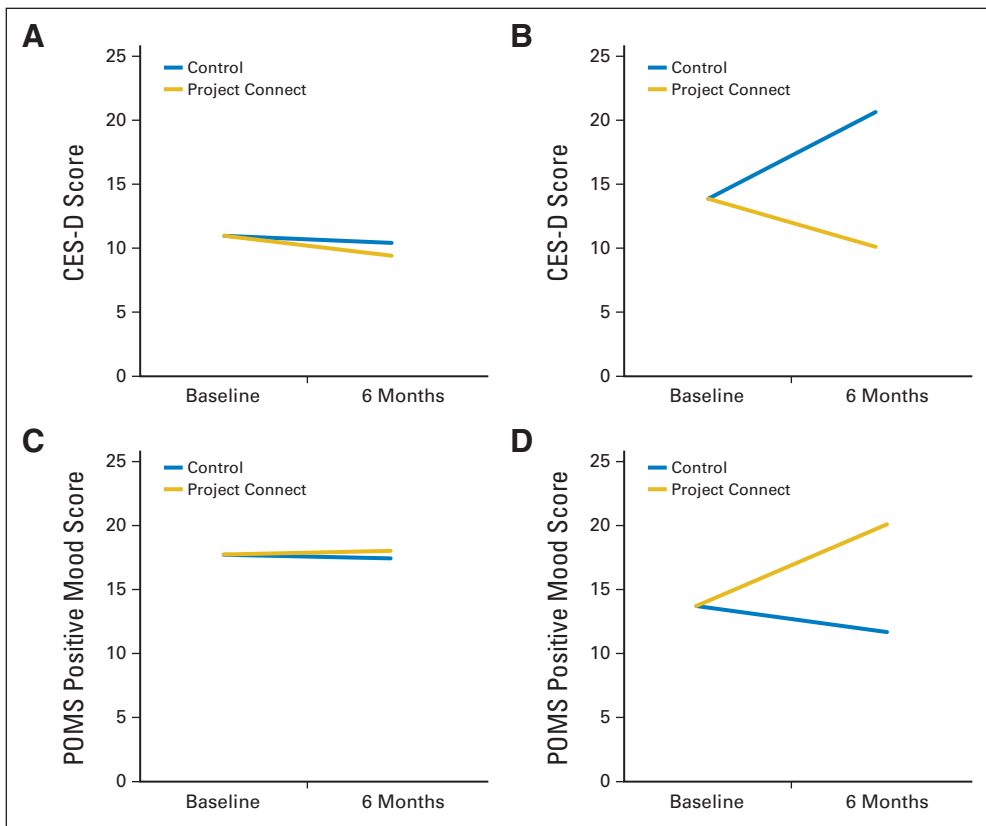


Fig 2. Adjusted mean scores on (A, B) depressive symptoms (Center for Epidemiologic Studies Depression Scale [CES-D]) and (C, D) positive mood (Profile of Mood States [POMS]) for patients (A, C) with no current medical treatment and (B, D) in current medical treatment, as a function of intervention (Project Connect Online v waiting-list control) and current medical treatment (yes v no).

notable in that they were obtained through intent-to-treat analyses of all randomized participants, including six of 46 assigned to PCO who did not attend the workshop, were evident 6 months after participation in a brief intervention, and emerged on both general and cancer-related measures of psychological adjustment. In addition, these effects were moderate to large in magnitude.³¹ These effects, however, were conditioned by significant interactions, which revealed benefits of PCO particularly (or solely) for women in active medical treatment, most of whom had metastatic disease. Motivations to tell one's story, express cancer-related emotions, garner support, and keep others informed likely are stronger during active medical treatment and the often uneven course of metastatic disease than when treatment is complete. Anecdotally, several longer term survivors stated they participated more for altruistic than personal reasons. Approaches are needed to reduce potential barriers to personal Web site use for patients in active medical treatment (eg, engaging a loved one to manage some Web site functions) and to promote effective use among survivors not in current treatment (eg, address remaining needs for support).

Several limitations of the trial are apparent. This preliminary study had sufficient statistical power to detect only moderate to large effects, and it did not include multiple-test adjustment. In light of trends on some dependent variables, it is possible that PCO has the potential for positive effects on a broader range of general and cancer-related outcomes. The waiting-list control condition did not control for attention. Generalizability of findings to men, individuals with diverse cancer diagnoses, and disadvantaged groups (eg, low education) awaits future research. Effects on outcomes other than self-

reported adjustment (eg, return to work) require study, as does sustainability of effects beyond 6 months.

To our knowledge, the current research represents the first experimental study of an innovative intervention with high potential for dissemination. Several questions remain, however, including whether the enhanced benefit for individuals in current medical treatment and/or with metastatic disease is a reproducible effect; potential ethnic/cultural and sex-related variation in effects, in light of nuances in support processes (eg,^{12,32}); effects on other outcomes, including physical health; and comparative effects of this intervention versus other online or in-person approaches.^{33,34} Such continued research is warranted in light of the promising findings of this preliminary trial.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

Conception and design: Annette L. Stanton, John S. Link, James R. Waisman

Provision of study materials or patients: John S. Link, James R. Waisman

Collection and assembly of data: Annette L. Stanton, Elizabeth H. Thompson

Data analysis and interpretation: Annette L. Stanton, Elizabeth H. Thompson, Catherine M. Crespi

Manuscript writing: All authors

Final approval of manuscript: All authors

REFERENCES

1. Helgeson VS, Cohen S: Social support and adjustment to cancer: Reconciling descriptive, correlational, and intervention research. *Health Psychol* 15:135-148, 1996
2. Alferi SM, Carver CS, Antoni MH, et al: An exploratory study of social support, distress, and life disruption among low-income Hispanic women under treatment for early stage breast cancer. *Health Psychol* 20:41-46, 2001
3. Nosarti C, Roberts JV, Crayford T, et al: Early psychological adjustment in breast cancer patients: A prospective study. *J Psychosom Res* 53:1123-1130, 2002
4. Cordova MJ, Cunningham LL, Carlson CR, et al: Posttraumatic growth following breast cancer: A controlled comparison study. *Health Psychol* 20:176-185, 2001
5. Widows MR, Jacobsen PB, Fields KK: Relation of psychological vulnerability factors to post-traumatic stress disorder symptomatology in bone marrow transplant recipients. *Psychosom Med* 62:873-882, 2000
6. Lutgendorf SK, Sood AK: Biobehavioral factors and cancer progression: Physiological pathways and mechanisms. *Psychosom Med* 73:724-730, 2011
7. Schmidt JE, Andrykowski MA: The role of social and dispositional variables associated with emotional processing in adjustment to breast cancer: An internet-based study. *Health Psychol* 23:259-266, 2004
8. Howsepian BA, Merluzzi TV: Religious beliefs, social support, self-efficacy and adjustment to cancer. *Psychooncology* 18:1069-1079, 2009
9. Stanton AL, Danoff-Burg S, Cameron CL, et al: Emotionally expressive coping predicts psychological and physical adjustment to breast cancer. *J Consult Clin Psychol* 68:875-882, 2000
10. Helgeson VS, Cohen S, Schulz R, et al: Group support interventions for women with breast cancer: Who benefits from what? *Health Psychol* 19:107-114, 2000
11. Manne S, Ostroff J, Sherman M, et al: Buffering effects of family and friend support on associations between partner unsupportive behaviors and coping among women with breast cancer. *J Soc Person Relat* 20:771-792, 2003
12. Wellisch D, Kagawa-Singer M, Reid SL, et al: An exploratory study of social support: A cross-cultural comparison of Chinese-, Japanese-, and Anglo-American breast cancer patients. *Psychooncology* 8:207-219, 1999
13. Marcus AC, Garrett KM, Kulchak-Rahm A, et al: Telephone counseling in psychosocial oncology: A report from the Cancer Information and Counseling Line. *Patient Educ Couns* 46:267-275, 2002
14. Caring Bridge. www.caringbridge.org
15. MyLifeLine.org Cancer Foundation: MyLife-Line. www.mylifeline.org
16. Høybye MT, Johansen C, Tjørnhøj-Thomsen T: Online interaction. Effects of storytelling in an internet breast cancer support group. *Psychooncology* 14:211-220, 2005
17. Not Sold Separately. www.notsoldseparately.com
18. WordPress. www.wordpress.org
19. Radloff LS: The CES-D Scale: A self-report depression scale for research in the general population. *Appl Psychol Measure* 1:385-401, 1977
20. McNair DM, Lorr M, Droppleman LF: EITS Manual for the Profile of Mood States. San Diego, CA, Educational and Industrial Testing Service, 1971
21. Sears SR, Stanton AL, Danoff-Burg S: The Yellow Brick Road and the Emerald City: Benefit-finding, positive reappraisal coping, and posttraumatic growth in women with early-stage breast cancer. *Health Psychol* 22:487-497, 2003
22. Stanton AL, Danoff-Burg S, Huggins ME: The first year after breast cancer diagnosis: Hope and coping strategies as predictors of adjustment. *Psychooncology* 11:93-102, 2002
23. Stanton AL, Danoff-Burg S, Sworowski LA, et al: Randomized, controlled trial of written emotional expression and benefit-finding in breast cancer patients. *J Clin Oncol* 20:4160-4168, 2002
24. Stanton AL, Estes MA, Estes NC, et al: Treatment decision making and adjustment to breast cancer: A longitudinal study. *J Consult Clin Psychol* 66:313-322, 1998
25. Stanton AL, Snider PR: Coping with a breast cancer diagnosis: A prospective study. *Health Psychol* 12:16-23, 1993
26. Horowitz M, Wilner N, Alvarez W: Impact of Event Scale: A measure of subjective stress. *Psychosom Med* 41:209-218, 1979
27. Tedeschi RG, Calhoun LG: The Posttraumatic Growth Inventory: Measuring the positive legacy of trauma. *J Traumatic Stress* 9:455-472, 1996
28. Schafer JL: *Analysis of Incomplete Multivariate Data*. New York, NY, Chapman and Hall, 1997
29. Rubin DB: Inference and missing data. *Biometrika* 63:581-592, 1976
30. Rubin DB: *Multiple Imputation for Nonresponse in Surveys*. New York, NY, John Wiley & Sons, 1987
31. Cohen J: *Statistical Power Analysis for the Behavioral Sciences* (ed 2). Hillsdale, NJ, Erlbaum, 1988
32. Taylor SE, Sherman DK, Kim HS, et al: Culture and social support: Who seeks it and why? *J Pers Soc Psychol* 87:354-362, 2004
33. Leykin Y, Thekdi SM, Shumay DM, et al: Internet interventions for improving psychological well-being in psycho-oncology: Review and recommendations. *Psychooncology* 21:1016-1025, 2012
34. Hong Y, Peña-Purcell NC, Ory MG: Outcomes of online support and resources for cancer survivors: A systematic literature review. *Patient Educ Couns* 86:288-296, 2012

Acknowledgment

We thank the women who took part in the Project Connect Online trial, Kevin Durr and Not Sold Separately, Cheryl Jacobs and Lisa Donley of Breastlink Medical Group, and Lauren Gyllenhammer, Delana Parker, and Orly Weltfreid, who aided in performance of the research.

Appendix

Project Connect Online Intervention Development

Development of the Project Connect Online intervention was informed by two preliminary phases of the research involving semistructured interviews of eight patients with breast cancer who had created personal Web sites to communicate about the cancer experience and focus groups of seven patients with breast cancer to evaluate barriers, facilitators, and preferences for creating personal Web sites. First, semistructured interviews of approximately 60 minutes were conducted with eight women diagnosed with breast cancer who had created their own personal Web sites to communicate with their social network about the cancer experience (phase 1). They were recruited from community clinical oncology practices and listservs for women with cancer (eg, bcmets.org). The principal investigator (A.L.S.) conducted the interviews in person or by telephone with the goals of learning about the intended purposes, benefits, challenges, and consequences associated with Web site use. Second, the researchers (A.L.S. and E.H.T.) conducted two 90-minute focus groups with a total of seven patients with breast cancer from the community medical oncology practice who were interested in the creation of personal Web sites (phase 2). Focus group members discussed perceived barriers, facilitators, and preferences for creating personal Web sites and reviewed sample Web sites volunteered by the phase 1 participants. The researchers prompted suggestions for functions of the Web sites and the format and content of the Project Connect Online intervention.

Review of the recorded phase 1 and 2 sessions by the researchers informed the development of Web site functions and esthetics, as well as intervention content and format. Specifically, suggestions from phase 1 and 2 participants resulted in decisions to (1) offer the intervention to all interested women diagnosed with breast cancer regardless of diagnosis duration or treatment status rather than only to women in active medical treatment (consequently, medical treatment status was examined as a moderator of the intervention's effects); (2) allow attendance at intervention sessions by significant others (eg, partners, offspring); (3) proactively address participants' concerns about Web site use, including perceived pressure to post frequent Web site updates, perceived expectation to adopt a particular tone in journal entries (eg, cheerful, wise, eloquent, positive), discomfort requesting help, perceived responsibility to respond individually to Web site visitors, disappointment arising from the lack of or content of responses from particular individuals in the social network; and (4) provide options for Web site privacy settings (no individual Web site was accessible through general search engines; participants could elect password protection for entry to their Web sites).

Incorporating these decisions, the researchers collaborated with a Web site development firm,¹⁷ using the WordPress personal publishing platform,¹⁸ to develop a Web site design that allowed for personalization with regard to esthetics and content (eg, Web site template, title, links). Each of the 11 potential WordPress Web site templates selected by the researchers were designed to contain six identical functions (1): a journal (blog) into which photos could be inserted; (2) Web site links chosen by the women, with a list of cancer information Web sites also offered by the researchers (eg, Web sites of the oncology clinic, National Cancer Institute, American Society of Clinical Oncology public site); (3) a How You Can Help page, in which participants could convey actions Web site visitors could undertake for the participant (eg, meal provision, written cards, transportation); (4) choice of privacy settings; (5) instructions for visitors to subscribe to receive automatic notification of updates to the Web site and to post personal messages to the participant; and (6) an online survey to assess visitors' reactions to the Web site (data not reported here). The researchers and Web site development firm created a 48-page manual with written and visual instructions for creating and maintaining the Web sites. In addition, the Web site development firm created online tutorials for managing several Web site functions (eg, adding a link or photo, writing a post, changing templates). The researchers (A.L.S. and E.H.T.) conducted a pilot intervention session with four phase 2 participants to elicit feedback on the online interface, the instructional manual, and session content; slight modifications were made before launching the intervention.

Details of the Multiple Imputation Procedures

The purpose of the multiple imputation was to support an intent-to-treat analysis that included all randomly assigned subjects in the presence of missing outcomes for some participants. Missingness on baseline variables was negligible, whereas outcomes at 6 months were missing for 12 participants (14% of the total of 88 randomly assigned patients) owing to dropout and partially missing data for one participant owing to incomplete assessments.

Missing data were imputed using Markov chain Monte Carlo (MCMC) full-data imputation²⁸ as implemented in the MI procedure in SAS software version 9.3. This method assumes multivariate normal data and uses a Bayesian approach and MCMC to create draws from the posterior distribution of the missing data. Technical details are provided in Schafer²⁸ and in SAS/STAT(R) 9.3 User's Guide, available online at http://support.sas.com/documentation/cdl/en/statug/63,962/HTML/default/viewer.htm#mi_toc.htm. Although the MCMC method assumes multivariate normality, inferences are robust to departures from multivariate normality if the amount of missing information is not large.²⁸

Variables selected for the imputation model included variables in the complete data model and variables correlated with the target missing variables. These included both variables that were collected only at baseline and variables that were collected at all three assessments. Longitudinal data were in the wide format (one row per subject) for purposes of the imputation. Variables included in the

imputation model included sociodemographic characteristics (education, age, race/ethnicity, income, employment status), cancer-related and medical variables (diagnosis duration, stage, surgery, chemotherapy, radiotherapy, Herceptin, tamoxifen, whether currently in medical treatment), familial/social network data (marital status, years married, whether had children, whether had children living at home, living parent, living sibling, close living relatives, support group attendance ever, current support group attendance), outcome measures at all available time points, that is, baseline, 1 month, and 6 months (Center for Epidemiologic Studies Depression, Profile of Mood States–Negative Mood, Profile of Mood States–Vigor, Impact of Events Scale [Intrusion], Posttraumatic Growth Inventory Relating to Others Subscale, Posttraumatic Growth Inventory Life Appreciation Subscale), additional psychosocial variables potentially related to outcomes or missingness (seen mental health professional ever, seeing mental health professional now, loneliness, social support, coping self-confidence), and group assignment.

We obtained 30 imputations of missing values after burn-in of 1,000 iterations. The relative efficiency of using 30 imputations rather than an infinite number for fully efficient imputation exceeded 0.993 for all parameters. Convergence was checked by examining trace plots and autocorrelations for parameter values.

The analytic approach was an analysis of covariance, with the 6-month measure as dependent variable and group assignment (Project Connect Online or control group), current medical treatment (radiotherapy, chemotherapy, biologic therapy [endocrine therapy not counted]: yes/no), their interaction, and the baseline measure as independent variables. Main effects were estimated as adjusted mean differences between levels of each factor. When the interaction was significant, we estimated differences in adjusted means among pairs of the four cells defined by the interaction. Because sample sizes among the cells defined by Project Connect versus control condition and current medical treatment (yes/no) were unequal, we used type III sums of squares and the parameters of interest for inference were adjusted means, also known as least square means. Adjusted means are a type of linear combination of regression parameter estimates, and as such, point estimates and SEs can be obtained for them, and the point estimates and SEs obtained from multiply imputed data sets can be combined using Rubin rules.^{29,30} In SAS, these results can be obtained using the MIXED procedure; syntax is provided at <http://support.sas.com/kb/30/698.html> and <http://support.sas.com/kb/30/715.html>. After the 30 complete data sets were analyzed using the MIXED procedure, the MIANALYZE procedure was used to combine the results from the 30 analyses using Rubin rules.

To validate the multiple imputation results, the process was repeated with different starting values for the random number generator, and sensitivity analyses were conducted by repeating the multiple imputation using different model specifications. All procedures gave similar results.

Table A1. Results of Outcome Analysis for Project Connect Online Based on Data of Participants Retained at 6 Months (n = 75)

Outcome	Main Effect of Group Assignment						Main Effect of Current Treatment Status						Interaction, P		
	PCO (n = 40)		Control (n = 35)		Cohen d	95% CI	Current Treatment (n = 16)		Not in Treatment (n = 59)		Cohen d	95% CI			
	Adjusted Mean	SE	Adjusted Mean	SE			P	Adjusted Mean	SE	Adjusted Mean				SE	P
CES-D	9.6	1.5	16.0	1.5	.004	0.7	0.2 to 1.2	15.6	1.9	10.0	1.0	.01	0.6	0.1 to 1.1	.02
POMS-Negative Mood	22.1	3.8	35.1	3.9	.02	0.5	0.1 to 0.9	32.3	4.9	25.0	2.5	.19	0.3	−0.1 to 0.7	.03
POMS-Vigor	18.9	1.3	14.4	1.3	.02	0.5	0.1 to 1.0	15.6	1.6	17.7	0.8	.27	0.2	−0.2 to 0.7	.06
Impact of Event Scale (Intrusion)	8.4	1.1	11.5	1.2	.06	0.4	0.0 to 0.9	11.3	1.4	8.6	0.7	.10	0.4	−0.1 to 0.8	.90
PTGI Relating to Others Subscale	23.5	1.1	21.4	1.1	.18	0.3	−0.1 to 0.7	21.7	1.4	23.1	0.7	.38	0.2	−0.2 to 0.6	.20
PTGI Life Appreciation Subscale	10.5	0.4	8.5	0.4	.002	0.6	0.2 to 0.9	8.9	0.5	10.1	0.3	.05	0.4	0.0 to 0.7	.03

Abbreviations: CES-D, Center for Epidemiologic Studies Depression Scale; PCO, Project Connect Online; POMS, Profile of Mood States; PTGI, Posttraumatic Growth Inventory.

Table A2. Effect Sizes for Outcomes With Significant Interaction Effects

Outcome	Adjusted Cell Mean				Cohen <i>d</i> Effect Sizes, Differences in Adjusted Cell Means					
	A. PCO and Current Treatment (n = 8)	B. Control and Current Treatment (n = 8)	C. PCO and Not in Treatment (n = 32)	D. Control and Not in Treatment (n = 27)	PCO v Control for Participants in Treatment (A v B)	PCO v Control for Participants Not in Treatment (C v D)	Current Treatment v not in Treatment for Control Group Assignees (B v D)	Current Treatment v Not in Treatment for PCO Group Assignees (A v C)	PCO Assignees in Treatment to Control Assignees Not in Treatment (A v D)	Control Assignees in Current Treatment to PCO Assignees Not in Treatment (B v C)
CES-D										
Mean	9.8	21.4	9.3	10.6	1.3	0.1	1.2	0.0	0.1	1.3
SE	2.8	2.6	1.3	1.4						
95% CI					0.4 to 2.1	-0.3 to 0.6	0.5 to 1.8	-0.7 to 0.6	-0.6 to 0.8	0.7 to 1.9
<i>P</i>					.003	.53	.0006	.89	.80	.0001
POMS-Negative Mood										
Mean	19.6	44.9	24.5	25.4	1.0	0.0	0.7	0.2	0.2	0.8
SE	6.8	6.9	3.4	3.7						
95% CI					0.2 to 1.7	-0.3 to 0.4	0.1 to 1.3	-0.4 to 0.8	-0.4 to 0.8	0.2 to 1.4
<i>P</i>					.01	.86	.02	.52	.46	.01
PTGI Life Appreciation Subscale										
Mean	10.6	7.2	10.4	9.8	1.0	0.2	0.8	0.0	0.2	0.9
SE	0.8	0.8	0.4	0.4						
95% CI					0.3 to 1.6	-0.2 to 0.5	0.3 to 1.2	-0.4 to 0.5	-0.3 to 0.7	0.4 to 1.4
<i>P</i>					.003	.31	.004	.85	.40	.0004

NOTE. Estimates are from general linear models with measurement at 6-month assessment as dependent variable and baseline measurement, group assignment, current medical treatment status, and the interaction between group assignment and current treatment status as independent variables. Means are adjusted for other effects in the model by holding such effects constant at their marginal means. Cohen's *d* effect sizes provide the effects on a pooled standard deviation scale. Abbreviations: CES-D, Center for Epidemiologic Studies Depression Scale; PCO, Project Connect Online; POMS, Profile of Mood States; PTGI, Posttraumatic Growth Inventory.