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EFFICACY TRIAL OF AN INTERNET-BASED INTERVENTION FOR CANCER-RELATED FEMALE SEXUAL DYSFUNCTION

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Abstract

The recent National Comprehensive Cancer Network Survivorship Guideline recommends systematic evaluation and multidisciplinary treatment of cancer-related sexual dysfunctions. Yet, most oncology professionals fail to routinely assess sexual problems and lack expertise to treat them. An internet-based intervention was designed to educate female patients and their partners about cancer-related sexual problems, to describe medical treatment options and how to find expert care, and to provide self-help strategies. A randomized trial assessed efficacy of the intervention when used as self-help versus the same web access plus three supplemental counseling sessions. Survivors of localized breast or gynecological cancer completed online questionnaires at baseline, post-treatment, and 3- and 6-month follow-up, including the Female Sexual Function Index (FSFI); the Menopausal Sexual Interest Questionnaire (MSIQ), the Brief Symptom Inventory-18 (BSI-18) to assess emotional distress, and the Quality of Life in Adult Cancer Survivors Scale (QLACS). Program evaluation ratings were completed post-treatment. Fifty-eight women completed baseline questionnaires (mean age 53 ± 9). Drop-out rates were 22% during treatment and 34% at 6-month follow-up. Linear mixed models for each outcome across time showed improvement in total scores on the FSFI, MSIQ, and QLACS ($P<0.001$) and BSI-18 ($P=0.001$). The counseled group improved significantly more on sexuality measures, but changes in emotional distress and quality of life did not differ between groups. Program content and ease of use were rated positively. Research is needed on how best to integrate this intervention into routine clinical practice, particularly how to improve uptake and adherence.

Keywords

female sexual dysfunction; cancer survivorship; internet intervention

Female sexual dysfunction is very common after cancer treatment. Two-thirds of the seven million female cancer survivors in the United States were treated for breast, gynecological, bladder, or colorectal malignancies.[1] At least 50% experience long-term, severe sexual problems.[2-4] The most common dysfunctions are vaginal dryness and pain and decreased sexual desire.[2,5,6] The risk of sexual dysfunction is increased by abrupt ovarian failure,[5,6] severe vaginal atrophy from using aromatase inhibitors,[7] direct genital damage from pelvic radiation therapy,[8-10] and genital graft-versus-host disease.[11] Urinary and fecal incontinence often lead to avoidance of sexual contact.[12]

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The recent National Comprehensive Cancer Network Survivorship Guideline advocates systematic assessment of female sexual function and referral for multidisciplinary treatment.[13] Unfortunately, women with cancer report few satisfying discussions about sexuality.[14,15] Fewer than 20% of sexually dysfunctional women treated for cancer seek professional help [3,16,17] and distress over sexual dysfunction ranks high in surveys of unmet needs of cancer survivors.[18,19] Only a few gynecologists and mental health professionals have expertise in managing relevant physical symptoms[20,21] or in providing evidence-based cognitive behavioral treatment. [22-24] Insurance coverage is poor, especially for mental health services.

An internet-based intervention may be a cost-effective way for oncology settings to comply with the new guidelines. We recently demonstrated that an internet-based intervention with couples after prostate cancer using email contact with the therapist was as effective in improving sexual function as three in-person sessions of cognitive-behavioral therapy.[25] Pilot studies with internet-based interventions for female sexual dysfunction have showed promise for women unselected for health[26] and in gynecologic cancer survivors.[27,28] We created a web site, *Tendrils: Sexual Renewal for Women after Cancer* and tested a prototype in a randomized trial, comparing usage on a self-help basis or supplemented with sexual counseling. We hypothesized that both groups would improve on self-report measures of sexual function and satisfaction, but that the counseled group would have a significantly larger gain.

MATERIALS AND METHODS

The research protocol, including recruitment materials and web site content, was approved by the UT MD Anderson Institutional Review Board (IRB). All participants provided informed consent. No adverse events were reported. Eligible women were one to seven years post-diagnosis of localized breast or gynecological cancer, and off active treatment other than hormonal therapy. They scored as sexually dysfunctional (under 26.5) on the Female Sexual Function Index,[29] had been in a sexual relationship for at least 6 months, and had a partner willing to participate in behavioral homework. They lived close enough to attend 3 in-person counseling sessions, could read English, and had internet access.

Recruitment

We recruited for the study for 16 months, sending introductory letters and flyers to 1,123 women from our tumor registry who met eligibility criteria for cancer type, stage, and date of diagnosis. We supplied flyers to the breast and gynecological outpatient clinics and approached some women during outpatient clinic appointments. The study was also listed on ClinicalTrials.gov. Of 117 women screened for eligibility, twenty-two (19%) declined participation and 23 (20%) were ineligible.

Study Design

All women used the web site for a 12-week treatment period. Half were adaptively randomized, using minimization,[30] to have 3 supplemental in-person counseling sessions. Minimization balanced treatment groups on the following factors: education (≥4-year college degree vs. no college degree), age (≤ 49 vs. ≥ 50), current menopausal status, and cancer site (breast vs. gynecologic).

Women completed questionnaires on the web site at baseline, at the end of treatment, and at 3- and 6-month follow-up. Participants received a $20 gift card on completing questionnaires at each follow-up. Items assessed background and medical history. The Female Sexual Function Index (FSFI) was the primary outcome measure.[29] A 19-item,

multiple-choice questionnaire with excellent internal consistency, discriminant validity, and test-retest reliability, the FSFI has been validated with female cancer patients.[31] Subscales measure sexual desire, arousal, lubrication, orgasm, satisfaction, and pain. The total score reflects both function and satisfaction. One limitation is that scores are negatively biased if women have not been sexually active with a partner in the past 4 weeks.[31] We also included the Menopausal Sexual Interest Questionnaire (MSIQ), a 10-item scale with excellent internal consistency and test-retest reliability, with subscales measuring desire, responsiveness (pleasure and orgasm), and satisfaction.[32] The BSI-18 assessed emotional distress with a Global Severity Index (GSI) summary score.[33] Norms are available for community samples and oncology patients. The Quality of Life in Adult Cancer Survivors (QLACS) scale yielded a summary score from its 47 items measuring global quality of life.[34,35] At post-treatment, women rated the *Tendrils* program on 12 Likert scales.

Description of the Intervention

The password-protected *Tendrils* web site included text, graphics, animations, and multicultural photographs and clipart. Instructions suggested an order for using the site, but women could navigate from the home page to sections describing the sexual and fertility consequences of their type of cancer and treatment; genital anatomy, including an interactive, vulvar self-portrait with pain and pleasure mapping; sex after menopause; managing vaginal dryness and pain (with detailed advice on vaginal moisturizers, lubricants, pelvic floor exercises, and dilators); causes and treatment options for loss of desire or orgasm problems; ways to improve body image; resuming sex comfortably using sensate focus exercises; sexual issues related to ostomies or incontinence; communication with sexual partners and health professionals; dating; lesbian relationships; and sex after childhood and adolescent cancer. Videos included 11 interviews with women cancer survivors and vignettes played by actors illustrating common problems and coping strategies.

A therapist manual provided overall guidance and content checklists for each of the three counseling sessions. Two master's-level mental health professionals provided counseling and were supervised weekly by the first author (LRS). Counselors guided women through the web site and discussed behavioral homework.

Statistical Analyses

Demographic and clinical characteristics were summarized with means, standard deviations, ranges, and frequencies, and compared between intervention groups by Fisher's test, t-test, or a Wilcoxon test depending on the data distribution. Questionnaires were not scored if more than an allowed number of items were missing. Linear mixed models (LMM) were conducted to assess within and between group score changes over time for each outcome.[36] LMM is widely used in analyzing correlated, longitudinal data because it accounts for missing data by incorporating random effects characterizing heterogeneity among subjects. Each outcome score was regressed onto time-period, treatment group, and a time by treatment interaction. Post-hoc analyses evaluated the changes across time points within and between groups. Similar LMM models analyzed the relationship of web site usage to outcomes.

RESULTS

Attrition over Time

Figure 1 summarizes the number of women who entered the study and attrition. Seventy-two women provided informed consent and were minimized to a treatment group. However, 14% in the self-help group and 25% in the counseled group dropped out without completing

baseline questionnaires (Fisher's Exact Test, P=0.372). For the 58 women who completed the baseline, attrition during the treatment period was similar in both groups (22%), but 34% did not complete 6-month follow-up questionnaires. To determine whether dropping out (defined as the last point at which a patient was missing data for all four questionnaires) was associated with specific participant characteristics, a discrete survival time model was conducted with terms for treatment group, each baseline questionnaire score, age, cancer site (breast vs. gynecologic), education (≥ 4-year college degree vs. < college), and time points. The area under the ROC curve was 0.885. The only significant factor was that younger women were more likely to drop out (OR=0.91, P=0.034). Even though groups were balanced on age, it was used as a covariate in outcome analyses,.

Demographic and Medical Factors

Table 1 presents demographic and medical factors characterizing the 58 women who completed baseline questionnaires. The self-help and counseled groups did not differ significantly on any variable. The sample was reasonably diverse (21% minority ethnicity), but quite well-educated. Eighty percent were treated for breast cancer.

Impact of Intervention on Questionnaire Scores

Our hypothesis was confirmed for sexual outcomes. When groups were combined, gains were significant from baseline to post-treatment on the FSFI (Effect=3.41, P<0.001) and MSIQ (Effect=6.54, P<0.001). Table 2 summarizes results of LMMs analyzing within group effects for total scores on each questionnaire. Figure 2 illustrates trends over time graphically for the two groups on each outcome measure. At post-treatment, total FSFI scores improved significantly (P<0.001) for the counseled group with a trend (P=0.054) in the self-help group (between-group difference, P=0.024). Although gains remained significant at 6-month follow-up, most women did not attain the 26.6 score considered to mark "normal sexual function."[29] We also examined FSFI results excluding women at each assessment who were not sexually active.[31] Although 40 fewer scores were included, the LMM analysis again revealed a significant treatment effect in the counseling group that was maintained over time. Figures 2a and b show FSFI total scores across time for all women versus only sexually active women.

For the MSIQ, within-group treatment effects were highly significant for counseled women (P<0.001) but fell short of significance for the self-help group (P=0.082) (between-group difference, P=0.011). However, improvement for counseled women regressed at 6-month follow-up whereas the self-help group improved slightly over time.

On nonsexual outcomes, distress (BSI-18 GSI scores) improved significantly across time (Effect=-2.96, P=0.001) as did the QLACS Total Score (Effect=-13.73, P<0.001). Table 2 shows that changes at post-treatment were only significant within the self-help group, however (GSI, P=0.011; QLACS summary score, P=0.008) with gains maintained at 6 months.

Utilization of the Web Site

Web site usage was electronically recorded, excluding time spent completing questionnaires. For each participant, total minutes of usage were calculated during the 12-week treatment period, between post-treatment and 6-month follow-up assessments, and across the entire study period. The treatment groups did not differ significantly on usage during the treatment period (self-help mean (SD): 108.6 (141.9), counseled: 143.4 (134.8). Usage across the entire study was very similar between groups, with the mean (SD) for the combined sample at 149.0 (157.1). However, between post-treatment and 6-month follow-up, the self-help

group spent significantly more minutes on the web site (self-help: 38.6 (60.9), counseled: 7.6 (17.7), P=0.015).

We performed linear regression analysis to determine if more time on site was associated with better outcomes on the FSFI and MSIQ. Models included terms for baseline or post-treatment score, usage time, intervention group, and their interaction. Usage time during a particular period was not associated with improvement on the FSFI or MSIQ. However, there was a trend (P=0.065) for usage time across the entire study period to be associated with improvement in the 6-month MSIQ. Greater web site usage in the self-help group post-treatment is also consistent with the improvement seen in their scores during that time, in contrast to backsliding in the counseling group.

Post-Treatment Program Ratings

Table 3 presents mean ratings by treatment group for 12 aspects of the intervention program. Ratings were in the positive range on all scales. The only significant difference between groups was that counseled women rated the intervention more positively on addressing emotional concerns. Women rated the counselors, in particular, as helpful and empathic.

DISCUSSION

This randomized trial suggests that an internet-based intervention can significantly improve sexual function and satisfaction in women with sexual dysfunction several years after treatment for breast or gynecologic cancer. Although supplemental in-person sexual counseling was associated with larger improvements during the treatment period, women in the self-help group were more likely to persist in using the web site during the next 6 months. Their outcome measures improved slowly during that period, in contrast with some backsliding for counseled women, particularly on the MSIQ. The intervention also reduced emotional distress and improved ratings of overall quality of life at post-treatment, particularly within the self-help group. Younger women were more likely to drop out of the study. Although younger cancer patients are more emotionally distressed,[37] baseline BSI-18 was not predictive of dropping out. Cancer disrupts more life roles for younger women, which may have interfered with taking time for the intervention.[37] Because of our sample size, we had limited power to identify demographic or medical factors that may influence the efficacy of the intervention.

Questionnaire scores indicate that our participants had severe and pervasive sexual problems, even compared to similar cohorts.[29,31,38,39] Although sexual function improved, most women did not achieve criteria for normalcy on the FSFI or MSIQ. However, the magnitude of improvement in the counseled group was quite similar to results of a 3-session, individual intervention using cognitive-behavioral sex therapy techniques with 31 survivors of gynecologic cancer.[38] As in that study, some backsliding occurred by 6 months, suggesting a need for relapse prevention.

Future research should focus on facilitating adoption of the intervention. Our accrual was disappointing. It was difficult to publicize the intervention in our large cancer center. Sending letters to potential women was our most successful recruitment strategy, but over half of women over 50 are sexually inactive.[40] With the proliferation of patient advocacy groups on the internet, social media may help publicize the intervention, within a cancer center and in the community.[41] The choice of an in-person counseling format may also have discouraged some women who expressed reluctance to come to the cancer center for extra appointments, probably accounting for the greater drop-out rate in the counseled group after women found out their assigned treatment arm. Counseling may be more appealing if delivered by phone,[42] email,[25] or in bulletin board[27,28] or realtime[43] internet groups.

Attrition also needs to improve. Some women do not want to complete questionnaires because of the time involved or the sensitive nature of some items, accounting for drop-outs among women who gave informed consent but then failed to complete the baseline questionnaires and women who finished the intervention but never completed a follow-up.[44] Non-adherence rates of 15% to 30% are common in randomized trials of interventions targeting psychological problems, with little evidence that attrition is worse in internet-based formats.[44,45] The next version of *Tendrils* will require fewer questionnaires and will use them interactively, prompting users to set short-term goals and to track their progress with self-report instruments.[45]

Web site usability may have also have been a limitation. Despite overall positive evaluation ratings, we used a beta version of software that when encrypted, no longer allowed searches by keyword or direct links from one part of the text to another. Usability testing at the National Cancer Institute laboratory revealed that the home page and navigation need reorganization. Text needs to be presented in shorter sections using more bullet lists.

Future research needs to identify the best formats for supplemental counseling. Adding human support enhances adherence to a range of eHealth interventions aimed at changing behavior, with self-guided interventions helping 15% or less of those who try them. [45] However, low intensity internet interventions attract people who do not seek professional help, sometimes stimulating them to get care.[46] In future effectiveness trials we intend to test a sequential multiple assignment randomized trial (SMART) model,[47] starting with self-help usage and adding medical referrals or more intensive behavioral treatment on patient request, when women fail to use the web site, or when outcome scores are poor. Although the web site is designed for patients, oncology health professionals can learn from it and use the therapist manual to get comfortable providing assessment, brief counseling, and referrals for multidisciplinary care. More extensive professional education can also be developed to implement the sexuality survivorship guideline.

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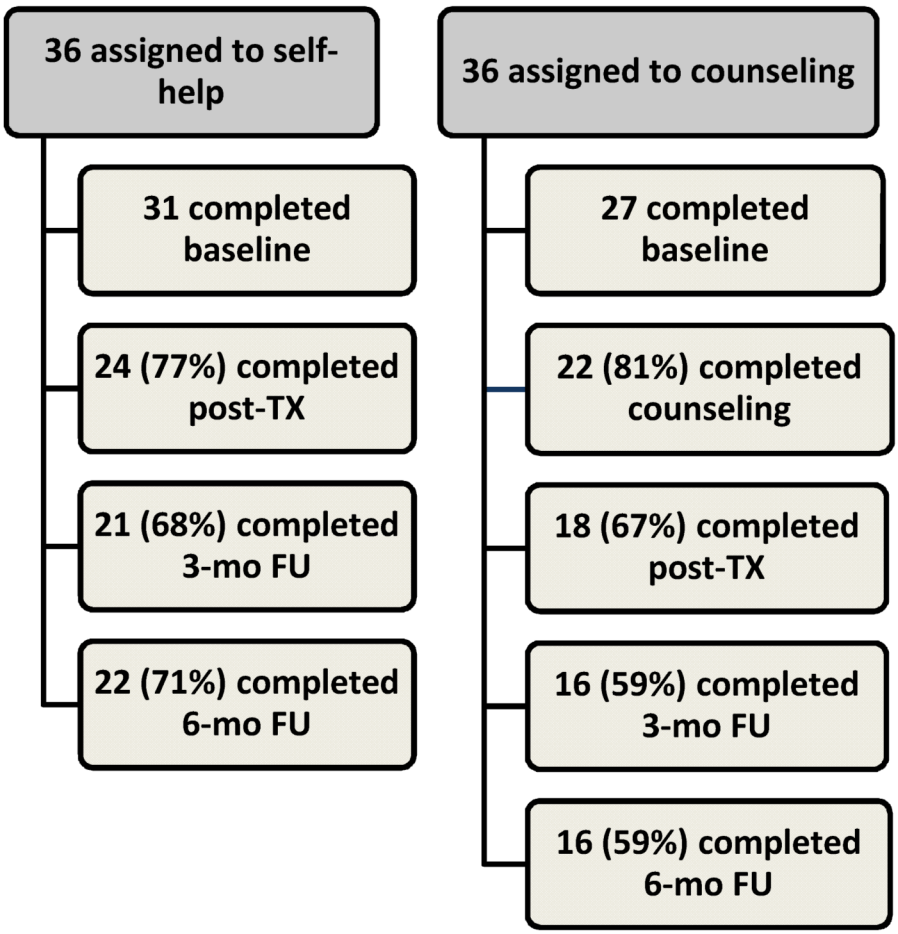

Figure 1. Attrition across Time

Abbreviations: Post-TX: Post-Treatment; 3-mo FU: 3-month follow-up; 6-mo FU: 6-month follow-up

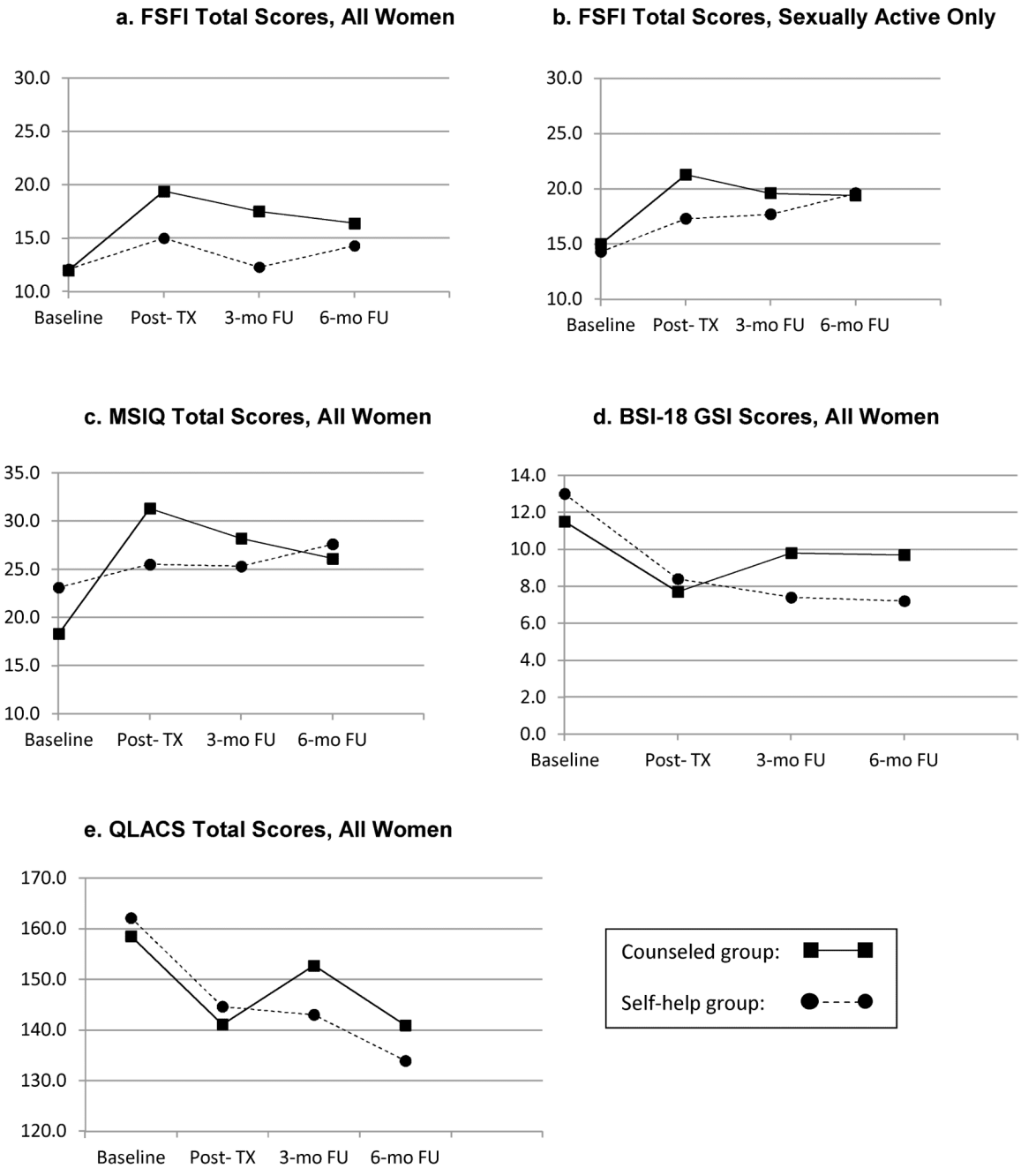

Figure 2. a through e: Mean Outcome Scores X Assessment Point X Treatment Group

a. FSFI Total Scores, All Women
b. FSFI Total Scores, Sexually Active Only
c. MSIQ Total Scores, All Women
d. BSI-18 GSI Scores, All Women
e. QLACS Total Scores, All Women

Abbreviations: FSFI: Female Sexual Function Index; MSIQ: Menopausal Sexual Interest Questionnaire; BSI-18 GSI: Brief Symptom Inventory-18 Global Severity Index; QLACS: Quality of Life for Adult Cancer Survivors; Post-TX: Post-Treatment; 3-mo FU: 3-month follow-up; 6-mo FU: 6-month follow-up

Table 1
Demographic and Medical Characteristics of the Sample

Characteristic	Self-Help (N=31)	Counseled (N=27)	Total (N=58)
Age: mean (SD) (range: 35 – 72)	54 (9)	52 (9)	53 (9)
Education			
≤ High school	13%	11%	12%
Some college	26%	33%	29%
4-year college	26%	30%	28%
Post-graduate	35%	26%	31%
Ethnicity			
White, non-Hispanic	74%	85%	79%
Hispanic American	13%	4%	9%
African American	10%	11%	10%
Asian American	3%	0%	2%
Marital Status			
Married	74%	89%	81%
Unmarried with partner	26%	11%	19%
Income			
≤ $50,000 year	28%	22%	25%
> $50,000 year	72%	78%	75%
Primary Cancer Site			
Breast	84%	78%	81%
Gynecologic *	16%	22%	19%
Cancer Stage			
0	13%	8%	10%
I	58%	48%	54%
II	16%	22%	19%
III	13%	22%	17%
Years since cancer diagnosis: mean (SD)	4.2 (5.2)	2.7 (1.7)	3.5 (4.1)
Current Menstrual Status			
Premenopausal	0%	7%	3%
Postmenopausal	100%	93%	97%
Hormonal cancer therapy			
Past tamoxifen	10%	10%	10%
Current tamoxifen	13%	26%	19%
Current aromatase inhibitor	3%	4%	3%
Past pelvic radiation therapy	3%	11%	7%

Characteristic	Self-Help (N=31)	Counseled (N=27)	Total (N=58)
Past Chemotherapy	67%	77%	71%
Comorbid health conditions **			
0	28%	28%	28%
1	59%	36%	48%
2	14%	32%	22%
3	0%	4%	2%
History of major depression	7%	16%	11%
Current psychotropic medication	27%	40%	33%
Current replacement hormones			
Estrogen pill or patch	3%	0%	2%
Vaginal estrogen	3%	11%	7%
Testosterone	3%	4%	4%

* Includes 2 cervical, 3 uterine, 4 ovarian, and 2 vulvar cancers

** Comorbidities: The sum of the following factors: psychotropic medication, hypertension, cardiovascular disease, major depression, diabetes, thyroid disease, a thma, arthritis, chronic lung disease, and hepatitis C.

Table 2

Summary of Linear Mixed Model (LMM) Analyses of Outcomes Within Treatment Group across Time

Questionnaire	Comparisons across Time	Contrasts for Counseled Group	P-value	Contrasts for Self Help Group	P-value
FSFI Total Score	Post-TX vs. Baseline	7.44	**<0.001**	2.75	**0.054**
	3-month vs. Post-TX	−1.39	0.446	−3.02	**0.050**
	6-month vs. Post-TX	−2.99	0.085	−1.05	0.489
MSIQ Total Score	Post-TX vs. Baseline	13.22	**<0.001**	3.43	0.082
	3-month vs. Post-TX	−3.20	0.198	−1.04	0.614
	6-month vs. Post-TX	−5.30	**0.018**	1.20	0.555
BSI GSI Score	Post-TX vs. Baseline	−2.63	0.139	−3.73	**0.011**
	3-month vs. Post-TX	1.52	0.443	0.01	0.995
	6-month vs. Post-TX	2.42	0.186	−1.14	0.465
QLACS Total Score	Post-TX vs. Baseline	−12.62	0.074	−15.95	**0.008**
	3-month vs. Post-TX	11.643	0.135	2.74	0.664
	6-month vs. Post-TX	5.93	0.415	−8.30	0.189

Abbreviations: Post-TX=post-treatment

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Table 3

Post-Treatment Evaluation Ratings of the Intervention Program*

Item	Self-Help N=24	Counseled N=19
Easy to understand	1.5 (0.5)	1.6 (0.6)
Medically correct	1.5 (0.5)	1.3 (0.5)
Gave info I needed to solve sexual problem	2.0 (0.7)	1.7 (0.7)
Addressed emotional concerns **	2.0 (0.9)	1.6 (0.5)
Would be valuable to partner	1.6 (0.7)	1.5 (0.5)
Helped understand medical treatment options	1.9 (0.6)	2.0 (0.7)
Survivor stories were helpful	1.9 (0.8)	1.9 (0.8)
Pictures and animations helped me understand	1.8 (0.6)	1.7 (0.8)
Was not overwhelmed by too much info	2.1 (0.7)	2.2 (0.6)
Sessions with counselor helped understanding	---	1.3 (0.4)
Counselor understood my feelings and concerns	---	1.1 (0.3)
Counseling helped with problems that would not have improved without *Tendrils*	---	1.4 (0.6)

* Rating Scale: 1=agree strongly 2=agree 3=disagree 4=disagree strongly

** P=0.048 between treatment groups