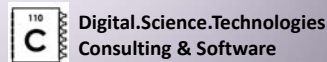




## SEXUAL RENEWAL FOR WOMEN AFTER CANCER: RANDOMIZED TRIAL OF A MULTIMEDIA, INTERACTIVE INTERVENTION

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## CANCER-RELATED SEXUAL PROBLEMS IN WOMEN

- 65% of over 7 million female cancer survivors in the United States were treated for breast, gynecological, bladder, or colorectal cancers (ACS, 2012)
- At least 50% have long-term problems with sexual function (2.3 million women) but <20% seek help
- Sexual problems are severe and long-term, including loss of desire and pleasure, vaginal dryness and pain, and (less often) trouble reaching orgasm
- 2013 National Comprehensive Cancer Network Survivorship Guideline: systematic assessment and treatment of sexual problems



## BARRIERS TO FINDING HELP

- Few gynecologists or other physicians understand these problems and how to treat them
- Few mental health professionals are cross-trained in psycho-oncology and sex therapy
- Insurance coverage is very poor for mental health services related to sexual dysfunction
- Limited info from internet or self-help books
- Sexual issues rank high in surveys of unmet needs of cancer survivors



## *Tendrils: Sexual Renewal for Women after Cancer*

A multimedia, interactive program presented on a web site. For women with any cancer type, from those at high genetic risk through long-term survivors, and their partners. Goals:

- Help women understand their sexual function and how their specific cancer treatment damages it
- Teach cognitive-behavioral self-help strategies
- Guide women in seeking medical help and choosing treatment options for problems such as loss of desire, genital pain during sex, and trouble reaching orgasm
- Give partners ways to participate in making sex better



## CONTENT

- Text: Literacy level, high school with glossary
- Animations, graphics, and multicultural photos, theme song with video
- 11 interviews videotaped with survivors
- 3 fictional cases with video vignettes illustrating common problems, communication skills, and coping strategies
- Reviewed by MD Anderson faculty for medical accuracy



## DESIGN OF STUDY

- Eligible participants: Treated for breast or GYN cancer, NED, off active cancer treatment except hormone therapy, sexually dysfunctional by questionnaire, have sex partner for  $\geq 6$  months
- Assigned to treatment group by minimization (adaptive randomization) to balance age, breast vs. GYN cancer, menopausal status
- *Tendrils* as self-help for 12 weeks, or *Tendrils + 3* hours of individual face-to-face counseling

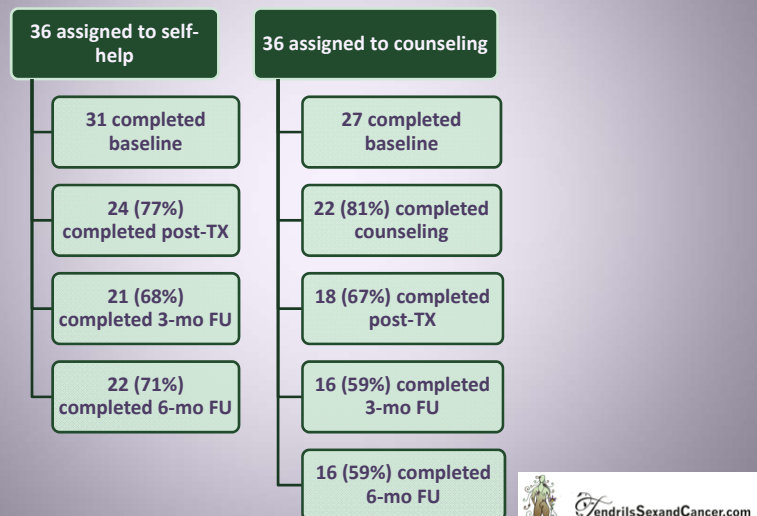


## OUTCOME MEASURES

- Assessment questionnaires completed on web site at baseline, end of 12-week treatment period, and at 3- and 6-month follow-ups
- Measured sexual function and satisfaction (FSFI and MSIQ), emotional distress (BSI-18), and quality of life as cancer survivors (QLACS)
- At 12 weeks rated program on 12 Likert scales
- Web site usage was electronically recorded



## ATTRITION: 117 screened, 22 (19%) declined and 23 (20%) ineligible



## DEMOGRAPHIC CHARACTERISTICS

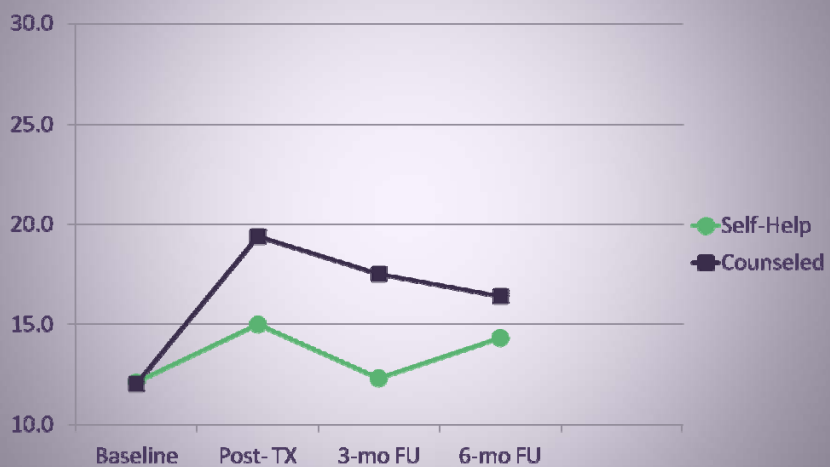
- No significant differences between treatment groups
- Mean age  $53 \pm 9$ , 89% married
- 79% Anglo, 9% AA, 10% Hispanic, 2% other
- 12% < HS, 29% some college, 59%  $\geq$  college
- 81% breast cancer, 19% GYN cancer
- 97% in menopause, 9% on estrogen, 4% testosterone

## Linear Mixed Models of Outcomes, Baseline to Post-Treatment, Combined Groups

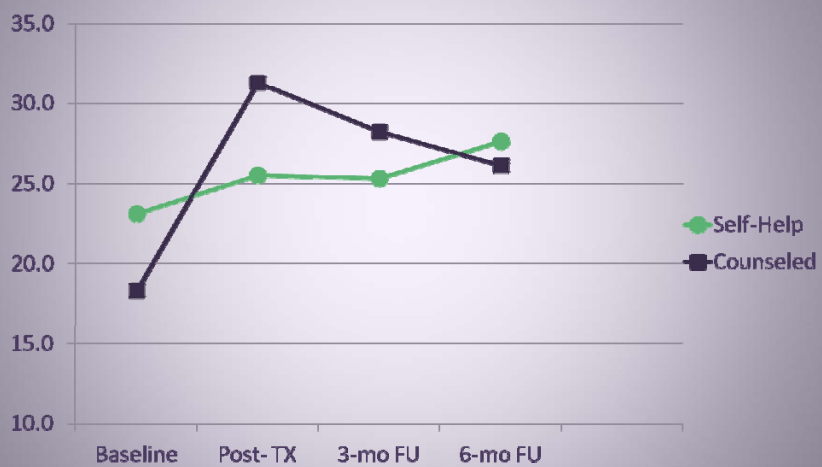
Outcome (Total Score)	Effect	P-level
FSFI	3.41	<0.001
MSIQ	6.54	<0.001
BSI-18	-2.96	0.001
QLACS	-13.73	<0.001

- Counseled group improved significantly more than self-help group on FSFI (P=0.024) and MSIQ (P=0.011)
- Gains remained significant from post-treatment to 6-month follow-up except for MSIQ in counseled group

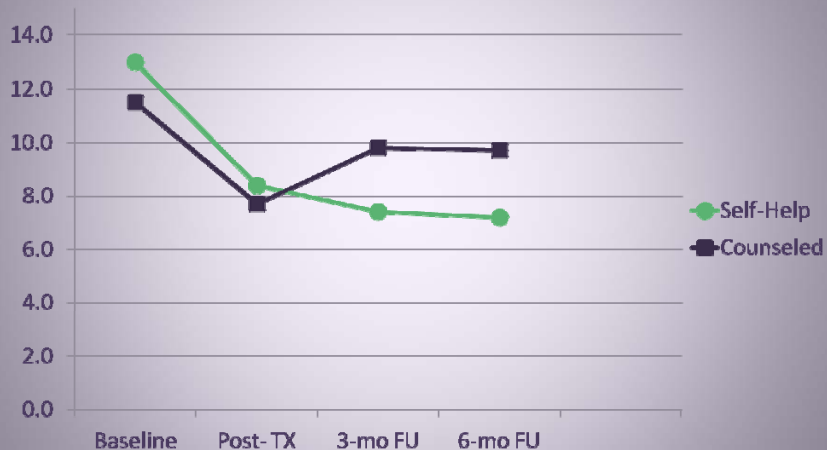
## FSFI by Group and Time



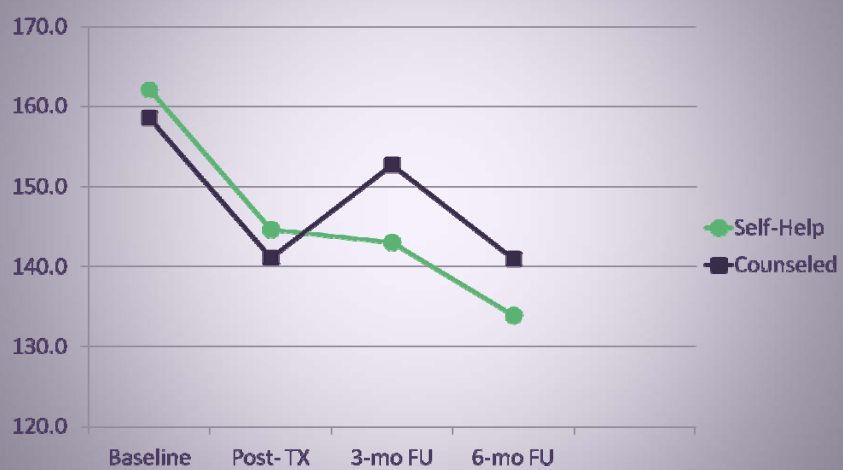
## MSIQ by Group and Time



## BSI-18 by Group and Time



## QLACS Total by Group and Time



## TIME SPENT ON WEB SITE

- Time spent on web site (excluding completion of questionnaires) electronically recorded
- Average was about 2.5 hours, highly variable
- Total usage time related to change in MSIQ at 6 months (P=0.06)

Group	Minutes during 12-week treatment	Minutes after 12-week treatment*	Total minutes
Self-Help	108.6 ± 141.9	38.6 ± 60.9	147.2 ± 174.5
Counseled	143.4 ± 134.8	7.6 ± 17.7	151.1 ± 137.7

\*P<.001 between groups

## PROMISING EFFICACY TRIAL

- *Tendrils* improves sexual function/satisfaction, particularly with supplemental counseling, but not to “normal” range, decreases emotional distress, improves cancer-related quality of life
- Women like and value the program
- Accrual disappointing and too much attrition
- Women disliked questionnaires and coming to cancer center for counseling
- Usability testing showed need for better navigation, shorter text sections, less clipart
- Plan to add goal-setting, tracking progress, and relapse prevention

