

# A Pilot Intervention Study to Improve Sexuality Outcomes in Breast Cancer Survivors

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## ABSTRACT

**Objective:** The main objective of the study is to assess the efficacy of the Permission, Limited information, Specific Suggestion, and sexual therapy (PLISSIT) model directly with breast cancer survivor (BCS) on sexual function and quality of life (QOL) domains. **Methods:** A pilot control trial was conducted comparing the PLISSIT model intervention to usual care. The intervention was delivered by two health professionals (nurse and professional sexual therapist) consisted of five sessions on counseling, genitalia anatomy, human sexual response, and sexual function. Data were collected before and 3 months after the intervention using the Female Sexual Function Index and the World Health Organization QOL-BREF questionnaire. **Results:** The sample consisted of 19 BCS (11 intervention, 8 controls) with a mean age of 54.5 8 years (standard deviation = 7.14) and the majority

were married, Black or mixed Brazilian, received chemotherapy, radiation and/or hormonal therapy, and education varied from high school to college. There was significant improvement in physical health ( $P = 0.031$ ), social relationships ( $P = 0.046$ ), orgasm ( $P = 0.055$ ), and pain ( $P = 0.049$ ) over time and the intervention resulted in improved arousal ( $P = 0.038$ ). **Conclusions:** The results suggest that the PLISSIT model may be an effective intervention for BCS in coping with and managing changes in sexuality and sexual function after treatment. It is important that nurses are aware of sexual intimacy concerns for BCS and integrate assessment into their nursing care.

**Key words:** Breast cancer, sexual counseling, sexuality, woman health

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## Introduction

Breast cancer is the most common type of cancer in women worldwide.<sup>[1,2]</sup> The incidence of breast cancer in South America is modest (46/100,000 age-standardized population) compared to that in the United States and Western Europe.<sup>[3]</sup> The 5-year survival rate for women with breast cancer has risen dramatically in Brazil to 87.4%.<sup>[4]</sup>

Today, as the survival rate for women with breast cancer increases, the treatment regimens are accompanied by a range of physical, psychological, existential, and social concerns. Body image, including the feelings of femininity and attractiveness, improves between 10 months and 3 years after surgery. Sexual attractiveness and feelings of comfort during sexual intimacy are most problematic over the first 1–2 years.<sup>[5]</sup>

Sexuality is normally an essential part of life.<sup>[5]</sup> As there has been a substantial increase in the number of breast cancer survivors (BCSs), it is critical to address their quality of life (QOL) after treatment.

There is a gradual improvement in QOL for many BCSs following primary and adjuvant therapies. However, persistent physical symptoms can result in psychological distress and poor QOL.<sup>[6]</sup> Specifically, alterations in sexuality and sexual function associated with breast cancer treatment adversely affect the physical, psychological, and social well-being domains of a woman's QOL.<sup>[6-9]</sup> This can result in sexual dysfunction, such as lower sexual interest, desire, pain, orgasm disorders, and decreased self-confidence.<sup>[8,9]</sup> Significant predictors of poor sexual function are vaginal dryness, poor marital/relationship satisfaction, and body stigma feelings.

Psychosocial interventions aimed at sexual rehabilitation that could focus on helping survivors address body shame and the associated avoidant behaviors, thereby facilitating adjustment, integration, and acceptance of their body, have been recommended.<sup>[10]</sup>

Complicating the physical and psychological distress associated with changes in sexuality and sexual function is the lack of communication about these issues with health-care providers.<sup>[6,11,12]</sup> There are resources available for nurses and physicians to initiate a conversation about sexuality. One resource is the Permission, Limited Information, Specific Suggestion, sexual therapy (PLISSIT) model, which provides a guide for patient-provider communication related to sexual and partner issues.<sup>[13-18]</sup> The PLISSIT model may be used directly to promote coping for those BCSs experiencing alterations in sexuality and sexual function. In addition, since mastectomy is the most common primary treatment for breast cancer in Brazil<sup>[19]</sup> and because of the possible negative effects of mastectomy on women's lives, this study explored the use

of the PLISSIT model with BCSs following a mastectomy and compared its impact on QOL and sexuality outcomes to that of usual care.

## Methods

### Design

A nonrandomized pre-/postpilot study was conducted. The study was approved by the Ethics Committee Assis Chateaubriand Maternity School in Fortaleza, Brazil, and was registered with the Brazilian Clinical Trials Registry (Registration No. RBR-33tdwy).

### Study population and sample

Eligible participants were BCSs who were >6 months since surgery, >18 years of age, and sexually active. BCS participants who were taking antidepressants or who had difficulty participating in two or more sessions and/or had scheduling difficulties were excluded. Sexually active was defined as a history of consensual penetrative vaginal intercourse, and it included masturbation.

The power calculation for the sample was based on a published study that reported mean scores for the Female Sexual Function Index (FSFI);<sup>[20]</sup> a sample of 10–22 was estimated with a power of 99.9% at the significance level of 5%.

### Procedures

The participants were recruited from December 08, 2016, to April 06, 2017. Recruitment flyers were posted in the breast cancer departments of Assis Chateaubriand Maternity School and the support group for BCSs, the Touch of Life Association (a nongovernmental organization). The participants from the breast cancer department contacted the researcher by phone from the information given on the flyers, while the participants from the Touch of Life Association were invited to attend and participate in the intervention group sessions during the association's monthly meeting.

A total of forty participants were eligible and recruited for the study. Seventeen participants declined to be included, and the remaining 23 participants were assigned to one of two groups. Of the remaining 23 participants, 15 participants were assigned to the intervention group, and 8 of the participants were assigned to the control group. Four participants were excluded from the intervention group because they attended <2 intervention sessions and one participant dropped out after 3 months as a result of scheduling difficulties [Figure 1]. All participants signed written informed consent forms. Questionnaires were administered to both groups of participants prior to the interventions and 3 months after baseline data collection.

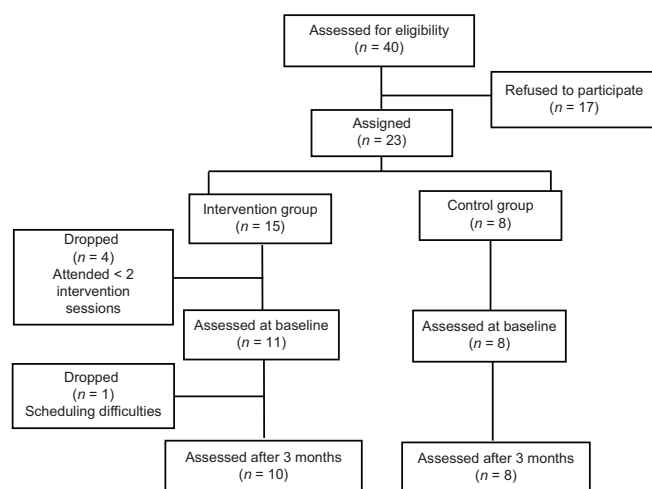


Figure 1: Participants flow diagram

### Intervention

The intervention consisted of the utilization of the Sexual Counselling Intervention for BCSs (SCIBCSs) that was based on the PLISSIT model.<sup>[21]</sup>

There were 5 weekly sessions, lasting approximately 1.5 h each [Table 1]. The SCIBCS followed a specific protocol and included counseling, information about genitalia anatomy, human sexual response, sexuality, and sexual function. There was adequate time to encourage and engage participants in the discussion of the information that was presented, and the presentations were followed with question and answer sessions. The counseling was performed by a licensed sexual therapist and by a registered nurse with a master's degree in nursing who was trained by the sexual therapist to conduct the session with her. The intervention was conducted in a BCS group setting. The PLISSIT model addressed both the biological and psychological aspects of sexuality and sexual function.<sup>[21]</sup>

The control condition was conducted during the monthly Touch of Life Association, and this meeting was conducted during March 2017. The control group received the same information as the intervention group, which was based on health education, using media resources as a tool to deliver the information. A health education lecture with sexuality as the main topic was presented and lasted approximately 2 h.

### Outcome measures

All measurements were administered in Portuguese using translated and validated versions of the original instruments.<sup>[22,23]</sup> The FSFI<sup>[22]</sup> was used to evaluate sexual function. It is composed of six subscales, and the sum of the scores measures the degree of desire, arousal, lubrication, orgasm, satisfaction, and pain (dyspareunia). The internal consistency of the scale has been established, with a Cronbach's alpha coefficient of 0.95. The total scores

Table 1: Sexual counseling intervention for breast cancer survivors protocol

Weeks' session	Description	Length
1 <sup>st</sup> week	The session was initiated by a dynamic presentation using the reversal of character technique. Each participant told characteristics about the person who sat beside them and introduced that person to the group. After the introductions, movie scenes with a mastectomized woman in moments of intimate relationship were shown. Later, questions were asked, such as: How is your sex life? How do you see your body and your sexuality? What kind of relationship you and your partner have? Do you think that you have something that bothers you in your sex life? What could you do to change this nuisance? Were there mood swings after your mastectomy? After your mastectomy, did you observe any change in your relationship with your partner?	1.5 h
2 <sup>nd</sup> week	The session started with welcome. The need to attend all meetings was reinforced. After the welcome, mannequins were used to execute the intervention. Pelvis and vaginas mannequins were used to clarify information about the female body and the practice and perception of masturbatory pleasure. At the end of the session, papers and pens were distributed to the participants. They wrote questions that were held until the next meeting	1.5 h
3 <sup>rd</sup> week	The session began with participants depositing their questions from the prior week into a box; these questions were addressed by a professional during the session. The questions were addressed seriously and specifically, and doubts that appeared were illuminated. An activity of self-image perception was conducted. Women drew their perceptions about themselves	1.5 h
4 <sup>th</sup> week	This session addressed an erotic practice technique. Women wrote an erotic story with the material that was claimed in a box and distributed among the women. The box was filled with resources such as heels, vibrators, lubricant, lingerie, and erotic material (whips, handcuffs, etc.,)	1.5 h
5 <sup>th</sup> week	This session went over all the other session topics. The professional brokered meetings with a professional sexual therapist for participants who were needing one-on-one monitoring	1.5 h

ranged from 2 to 36, with a higher score indicative of better sexual function. The Portuguese version of the FSFI was validated with Brazilian women and is indicated for use in clinical research.<sup>[22]</sup>

The World Health Organization QOL-BREF questionnaire (WHOQOL-BREF) consists of 26 questions; it has been translated and validated and its internal consistency, concurrent reliability, and content reliability have been established. The scale ranges from 0 to 100 and higher scores indicate a better QOL. The Cronbach's alpha for WHOQOL-BREF was 0.91.<sup>[23]</sup>

### Statistical analysis

The primary analytic approach was to describe and compare the means of WHOQOL-BREF and FSFI domains

between the two study groups (intervention and control) over time and by group. The variables included were from the WHOQOL-BREF (physical health, psychological, social relationships, and environment) and from the FSFI (desire, arousal, lubrication, orgasm, satisfaction, and pain). A *t*-test was used to compare mean values for the intervention and control groups. IBM SPSS Statistics for Windows version 22.0 (IBM Corp., Armonk, NY) was used, and significant results were reported at  $P < 0.05$ . To compare the variables over time, a general linear model was used. The significance level was set at  $\alpha = 0.05$  for all analyses. The homogeneity testing of the groups was analyzed using an independent sample *t*-test.

## Results

### Characteristics of the sample

The sample consisted of 19 BCSs (11 interventions and 8 controls), and there were no significant differences in demographic or cancer characteristics between the groups at baseline [Table 2]. The women were, on average, 54.58 years (standard deviation [SD] = 7.14), mixed-tone Brazilian (52.2%), and while not significant, more women in the intervention group were married compared to the control group. The average time since surgery was 7.07 years (SD = 4.97) years; the majority underwent radical mastectomy. Approximately, half of the women had breast reconstruction, and nearly, two-thirds received multimodality treatment (chemotherapy, radiation, and hormone therapy).

The mean QOL at baseline was rated as moderately good and was improved at 3 months in both groups ( $P = 0.02$ ). Physical health improved over time in both groups ( $P = 0.03$ ) as well as social relationships ( $P = 0.046$ ). Sexual function was rated as low in both groups at baseline, indicating a level of sexual dysfunction with no significant changes over time or by group assignment. Self-rated orgasm and pain improved over time in both groups ( $P = 0.05$ ), and there was a significant improvement in arousal in the intervention group compared to a decrease in the control group ( $P = 0.038$ ). Compared to the usual care group, the intervention group improved on arousal over time ( $P = 0.038$ ), and there was a trend toward less pain ( $P = 0.068$ ).

In summary, there were slight to moderate QOL improvements in both groups over time, and the findings suggest that the PLISSIT intervention improved arousal with a slight trend in pain improvement ( $P = 0.068$ ) [Table 3].

## Discussion

In our pilot clinical trial, the majority of women underwent radical mastectomy 95% and 47% had breast reconstruction. Gass *et al.*<sup>[24]</sup> compared QOL and sexuality outcomes in women who had a lumpectomy, mastectomy, or

Table 2: Demographics and cancer characteristics\* ( $n = 19$ )

Variables	<i>n</i>	Mean	SD	Median	Minimum	Maximum
Age						
Control	8	56.38	9.43	60	38	65
Intervention	11	53.27	5.00	54	45	60
Total	19	54.58	7.14	56	38	65
Time since surgery (years)						
Control	8	8.66	6.78	6.5	1.5	21
Intervention	11	5.91	2.95	5.0	2.0	11
Total	19	7.07	4.97	6.0	1.25	21
Variables	Control, <i>n</i> (%)	Intervention, <i>n</i> (%)	<i>P</i>			
Marital status						
Single	4 (50.0)	3 (27.27)	0.223 <sup>a</sup>			
Married/stable union	3 (37.5)	8 (72.73)				
Separated/divorced	1 (12.5)	0				
Skin tone						
White	1 (12.5)	3 (27.27)	0.699 <sup>a</sup>			
Mixed-tone Brazilian	4 (50.0)	6 (54.55)				
Black	3 (37.5)	2 (18.18)				
Education						
Elementary school	4 (50.0)	2 (18.18)	0.154 <sup>a</sup>			
High school	1 (37.5)	5 (45.46)				
College degree	3 (12.5)	4 (36.36)				
Type of mastectomy						
Simple	0	1 (9.09)	1.000 <sup>a</sup>			
Radical	8 (100)	10 (90.91)				
Breast reconstruction						
Yes	5 (62.5)	4 (36.36)	0.369 <sup>a</sup>			
No	3 (37.5)	7 (63.64)				
Treatment						
CT	0	2 (18.18)	0.172 <sup>a</sup>			
R	0	1 (9.09)				
H	0	0				
CT+R + H	6 (75.0)	5 (45.46)				
CT+R	2 (25.0)	0				
CT+H	0	2 (18.18)				
None	0	1 (9.09)				

\*Fisher's exact test, \*Demographics and cancer characteristics were collected at baseline. CT: Chemotherapy, R: Radiotherapy, H: Hormone therapy, SD: Standard deviation

mastectomy plus reconstruction. Their findings showed no significant difference in sexual functioning across the three surgical modalities. Although some subscales of the FSFI demonstrated higher scores for women who had lumpectomy versus mastectomy, our patients primarily had mastectomy.<sup>[24]</sup>

It is also unclear if surgery alone contributed to the sexuality outcomes, as 57.8% received multimodality therapy following surgery (chemotherapy, radiation, and hormonal treatment). It is important to highlight that chemotherapy is known to negatively affect sexuality and sexual function.<sup>[6-10]</sup> In a prospective study collecting data on QOL and sexual function during and after chemotherapy for breast cancer, decreased libido, increased discomfort, and adverse effects on pleasure, orgasm, and frequency of sexual activity were reported after therapy.<sup>[25]</sup>

**Table 3: Comparison of mean scores over time for the intervention and control groups (n = 19)**

Outcome measure	Baseline			3 months after baseline Postintervention			P*	
	n	Mean	SD	n	Mean	SD	Time	Group×time interaction
QOL								
Physical health								
Intervention	11	57.09	14.76	10	63.93	8.98	0.031	0.652
Control	8	52.23	13.08	8	60.27	11.20		
Psychological								
Intervention	11	70.98	7.88	10	72.17	11.49	0.198	0.189
Control	8	56.77	19.54	8	65.10	11.77		
Social								
Intervention	11	68.94	13.99	10	74.17	17.32	0.046	0.268
Control	8	64.58	13.91	8	78.13	10.85		
Environment								
Intervention	11	62.50	11.86	10	70.00	14.15	0.220	0.532
Control	8	52.73	11.26	8	62.50	11.86		
WHOQOL total score								
Intervention	11	64.88	7.84	10	70.07	10.11	0.022	0.352
Control	8	56.19	12.85	8	64.06	8.71		
Sexual function								
Desire								
Intervention	11	2.91	1.22	10	3.10	1.29	0.693	0.548
Control	8	2.69	1.22	8	2.63	1.03		
Arousal								
Intervention	11	2.18	1.67	10	2.63	1.67	0.772	0.038
Control	8	2.38	1.70	8	1.88	1.73		
Lubrication								
Intervention	11	2.16	1.55	10	2.50	1.58	0.470	0.335
Control	8	2.25	2.07	8	2.19	1.92		
Orgasm								
Intervention	11	2.12	1.76	10	2.53	1.57	0.055	0.976
Control	8	1.67	1.68	8	2.25	1.94		
Satisfaction								
Intervention	11	2.98	1.54	10	3.02	1.7	0.926	0.756
Control	8	3.25	1.21	8	3.13	1.31		
Pain								
Intervention	11	1.42	1.33	10	2.37	1.48	0.049	0.068
Control	8	2.00	2.14	8	2.04	2.12		
FSFI total score								
Intervention	11	13.78	7.89	10	16.14	2.82	0.269	0.231
Control	8	14.23	8.66	8	14.10	8.88		

\*General linear model. SD: Standard deviation, QOL: Quality of life, WHOQOL: World Health Organization Quality of Life, FSFI: Female Sexual Function Index

Our pilot study determined that the PLISSIT model is a clinically feasible and acceptable intervention.<sup>[12,15]</sup> Several studies have shown positive results of nurse-delivered psychoeducational interventions focused on the sexuality of cancer patients.<sup>[26]</sup>

More intense and longer interventions to improve sexuality outcomes in BCSs have been tested. In a sample of 169 BCSs who were >3 years since diagnosis, cognitive behavioral therapy delivered by professionals over 24 weeks improved sexual functioning, desire and arousal, and

decreased discomfort for the intervention group compared to the control group.<sup>[27]</sup>

These findings suggest that interventions are needed in clinical practice, as they have demonstrated the ability to improve outcomes for survivors, even several years after therapy. It is important for health-care professionals to be aware of problems related to sexual intimacy and to be prepared to not only provide information about these issues but also to reflect on expectations versus reality together with the women.<sup>[5]</sup>

### Limitations

There are three limitations: the small sample size, challenges with randomization, and the timing and scheduling of the hospital-based intervention sessions. Thus, some participants chose their group based on their preference and schedule. This was also not a prospective study, and it is unknown if an earlier intervention, such as immediately following therapy, might have provided more robust data to assess the type of interventions, and their effects on outcomes. Data were only collected on QOL and sexuality, and it is known that a breast cancer diagnosis and the psychosexual distress related to sequelae from treatment affect the partner and couple relationship.<sup>[28]</sup> No data were collected from the other participants in the partner relationship.

### Implication for practice and future research

Nurses need to be informed about the scope of the sexuality issues for BCSs and the critical need for screening assessment so that appropriate referrals or interventions can be initiated. It is especially important for nurses who practice globally in countries where they may have less autonomy or training in psychosocial-sexual responses of survivors. The preliminary findings of this study suggest that the PLISSIT model may be an effective intervention for BCSs. It is feasible in both the inpatient and outpatient settings for nurses, although system factors, educational gaps, and administrative support would need to be enhanced to effectively develop a plan to implement routine assessment.

The importance of sexual and vaginal health to QOL was reported by 87% of the participants in this study.<sup>[29]</sup> These women also reported a lack of knowledge about vaginal and sexual health promotion strategies. Thus, the use of the PLISSIT model was effective in addressing this gap in knowledge.

Future research should consider prospective longitudinal study designs and inclusion of other factors that might influence sexuality and sexual function outcomes, such as quality of the partner relationship, and data collected from partners, such as emotional well-being. Qualitative inquiry to explore experiences of BCSs and/or their partners and/or couples could provide a grounded perspective and could generate data on the best type, duration, and content of interventions, especially in culturally diverse populations.

Qualitative inquiry could also be conducted within an intervention trial to better understand the acceptability of the intervention and its valued components.

## Conclusion

The PLISSIT model had favorable effects on QOL and sexuality over the time. The results suggest the intervention might have an effective benefit for BCSs in coping with and managing changes in sexuality and sexual function after treatment. This study do provide nurses insight for the importance to integrate assessment of sexual intimacy into their nursing care for BCSs.

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## Conflicts of interest

There are no conflicts of interest.

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