Assessment of Sexual Dysfunction in Women Diagnosed with Breast Cancer

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I dedicate this thesis to my mother, who lost her long battle with breast cancer in 2010.
Your strength has always inspired me to keep going and to cope with challenges this life has to offer.
This thesis was no different.

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Statement of Candidate

I certify that I am the student whose name appears below and the work in this thesis titled *'Assessment of Sexual Dysfunction in Women Diagnosed with Breast Cancer'* has not been previously submitted for a degree nor has it been submitted as part of requirements for a degree to any other university or institution other than Macquarie University.

I also certify that this thesis is an original piece of research and has been conceptualized, implemented, analysed and written by me. Chapters 2, 3 and 4 of this thesis list two authors, Iris Bartula and A/Prof Kerry Sherman. Iris Bartula, the student submitting this thesis, is the primary author of each of these chapters and is responsible for preparation of each of the manuscripts. A/Prof Kerry Sherman supervised the development of all the studies and the writing of the abovementioned papers. Any other assistance that I have received in my research work and the preparation of the thesis has been appropriately acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

The research presented in this thesis was approved by the Macquarie University Human Research Ethics Committee, reference numbers: (1) 5201200487 on 13th September 2012 (Study 1); and, (2) 5201400594 on 26th June 2014 (Study 2)

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Thesis Abstract

Women with breast cancer frequently report sexual functioning difficulties that are directly or indirectly related to breast cancer and treatment. There are promising treatments for sexual dysfunction in women diagnosed with breast cancer, however, women who could benefit may not be identified as both practitioners and women find it difficult to initiate conversations about sexual functioning. One way to identify these women is to routinely administer a self-report scale to screen for sexual dysfunction. Unfortunately, there are numerous scales that have been used in research, with no one scale identified as a 'gold standard'. This thesis addresses this issue by developing a sexual dysfunction measure suitable for use with breast cancer populations.

An initial systematic review was conducted to identify potential scales for this purpose. Scales measuring sexual functioning in the breast cancer context were systematically evaluated to determine (1) evidence for acceptable psychometric properties; and, (2) the extent to which these scales cover the areas of sexual dysfunction defined by internationally-recognised diagnostic systems DSM-5 and ICD-10. The Female Sexual Function Index (FSFI) was identified as a promising measure.

The FSFI has been used extensively in breast cancer research, but never validated in this population. The first empirical study entailed a validation of the FSFI within the breast cancer context. Sexually active women diagnosed with breast cancer (N=399) completed an on-line questionnaire containing the FSFI and measures of related constructs necessary for validity studies. Overall, the FSFI demonstrated excellent internal consistency and test-retest reliability. The confirmatory factor analysis provided evidence for six factors – Desire, Arousal, Lubrication, Orgasm, Pain and Satisfaction. Convergent, divergent and discriminant validities were also evident. Women with breast cancer provided positive feedback about the FSFI and they noted that the FSFI could be further improved by including questions that measure (1) reasons for sexual dysfunction; (2) the contributions of the partner's difficulties; (3) the use of artificial lubricants; and, (4) pre-cancer sexual functioning.

Following suggestions for improvements to the FSFI for use with women with breast cancer, the second empirical study reports on the development and validation of the breast cancer adaptation of the FSFI – the FSFI-BC. This new measure aims to overcome the commonly-cited limitations of the original scale regarding applicability to non-sexually active women and measuring distress. Women diagnosed with breast cancer, both sexually active and non-active (N=596) completed the FSFI-BC and other measures of related constructs used for validity studies. An exploratory factor analysis provided evidence for seven factors - Changes after cancer, Desire/arousal, Lubrication, Orgasm, Pain, Satisfaction and Distress. Acceptable

internal consistency and test-retest reliability of the subscales were evident. The pattern of correlations with related constructs provided evidence for convergent and divergent validities. The participants provided positive feedback about the FSFI-BC.

Overall, the systematic review and two empirical studies of this thesis contributed to the understanding of the assessment of sexual dysfunction in breast cancer populations. The resulting scale, the FSFI-BC can be used in routine clinical care and research to screen for sexual dysfunction in women diagnosed with breast cancer, as it is psychometrically sound and appropriate for this population.

1.1 Breast Cancer Introduction

Breast cancer occurs when the cells in ducts and lobules of the breast grow abnormally and multiply (Cancer Australia, 2012). These cancer cells may be contained within the ducts of the breast (Ductal Carcinoma in Situ – DCIS), localized within the breast tissue (early breast cancer) or travel via the cardiovascular or lymphatic systems to other parts of the body, resulting in secondary (advanced or metastatic) breast cancer (Cancer Australia, 2012).

1.2 Breast Cancer Statistics

Breast cancer is the most frequently diagnosed cancer and the leading cause of cancer-related death in women, both in economically developing and developed countries (Jemal et al., 2011). Breast cancer incidence is typically higher in developed countries, which may be a result of variations in hormonal, reproductive and lifestyle risk factors, as well as diagnostic practices (Jemal et al., 2011). In Australia, about 13,500 women are diagnosed with breast cancer per year (Cancer Australia, 2012). Over the past 30 years, there has been a significant increase in breast cancer incidence worldwide as well as in Australia, which may have resulted from increased awareness and screening activity (Cancer Australia, 2012; Jemal et al., 2011). In Australia, women diagnosed with breast cancer are most likely to be 50-69 years of age, living in urban areas, having high socio-economic status and not of Aboriginal and Torres-Strait Islander descent (Cancer Australia, 2012).

Overall, 1 in 25 women who have died of any causes, would have been diagnosed with primary breast cancer, making it the second-leading cancer-related mortality cause and leading cause of disease burden in Australia (Cancer Australia, 2012). Over the past 30 years, there has been a noticeable decrease in breast cancer mortality, both worldwide and in Australia (Cancer Australia, 2012; Jemal et al., 2011). Consequently, 5-year survival rates have increased to 88%, with even higher survival rates recorded for early-stages breast cancer (Cancer Australia, 2012; Youlden et al., 2012). Decrease in mortality and improvement in survival rates are related to increasing breast-cancer awareness and screening practices, as well as improvement in medical treatments (Autier et al., 2010).

1.3 Breast Cancer Treatments

Breast cancer treatment usually involves a combination of surgical, radiation, chemotherapy and hormonal therapy approaches (Strom, Buzdar, & Hunt, 2008).

1.3.1 Surgical treatment

Surgical treatment for DCIS and early stage breast cancer usually involves breast conservation surgery (removing only affected tissue) or mastectomy (removing the entire breast), with similar survival and recurrence rates (Hunt & Meric-Bernstam, 2008; Tereffe & Strom, 2008). For secondary breast cancer, breast conservation therapy can be attempted following pre-operative chemotherapy to reduce tumour size (Hunt & Meric-Bernstam, 2008). For patients where biopsy reveals metastases in lymph nodes, axillary nymph node dissection may be performed (Hunt & Meric-Bernstam, 2008). Women can elect to undergo breast reconstruction immediately or some time after mastectomy (Hunt & Meric-Bernstam, 2008). Immediate reconstruction, using autologous tissue typically results in superior cosmetic outcomes and is more cost-effective in the long term (Chevray & Robb, 2008). Some commonly reported physical side-effects following breast surgery include pain, nausea and fatigue (Montgomery, Schnur, Erblich, Diefenbach, & Bovbjerg, 2010).

1.3.2 Radiation therapy

Radiation therapy plays an important role in breast-conservation surgery for early breast cancer and DCIS, with evidence suggesting better survival rates and reduced risk of recurrence in women receiving radiation therapy following their breast conservation surgery than in women having surgery alone (Tereffe & Strom, 2008). Radiation therapy is also used following mastectomy to treat subclinical tumours in the remaining tissue in order to prevent recurrence (Tereffe & Strom, 2008). Common side-effects reported following radiation therapy include: fatigue, skin itching (pruritis), peeling (desquamation), pigmentation and reddening (erythema), breast oedema, chest wall tenderness and pain (Hogle, 2007).

1.3.3 Chemotherapy

Chemotherapy has been found to benefit women with operable breast cancer, although the degree of benefit depends on individual factors, such as general health and tumour characteristics (Green & Hortobagyi, 2008). In early breast cancer, chemotherapy may be used as an adjuvant treatment, to eradicate any micrometastases (cancer that may have escaped the

breast tissue that cannot be detected with current imaging techniques), leading to elimination of relapse risk. For metastatic breast cancer, chemotherapy may be used to prolong remission (Green & Hortobagyi, 2008). More recently, the role of chemotherapy as a neoadjuvant treatment has been utilised, (Green & Hortobagyi, 2008) as means by which to reduce the tumour size, allowing for breast conserving surgery for bigger tumours (Green & Hortobagyi, 2008). Commonly, patients receive three to six months of chemotherapy treatment. Chemotherapy side-effects vary according to the chemical agent used (Green & Hortobagyi, 2008). Some of the commonly reported side-effects include: nausea, vomiting, inflamed and sore mouth (stomatitis), hair loss, loss of appetite, weight gain, nerve damage (neuropathy), reduction in bone marrow activity resulting in a decrease in production in white and red blood cells and platelets (myelosupression), formation of blood clots (thromboembolism), cardiac dysfunction, diarrhoea, constipation, cognitive decline, premature menopause, fatigue and muscle pain (Green & Hortobagyi, 2008; Kayl & Meyers, 2006; Partridge, Burnstein, & Winter, 2001).

1.3.4 Hormone therapies

Hormone therapies have been shown to improve outcomes for women with oestrogen and progesterone receptor positive breast cancers, and to be valuable in breast cancer prevention in women at risk of developing breast cancer (Pinder & Buzdar, 2008). In women diagnosed with breast cancer, hormone therapy is generally used for five years (with a possible extension for another five years for some patients), following chemotherapy, when risks of recurrence are intermediate or high (Cella & Fallowfield, 2008; Pinder & Buzdar, 2008). Although hormone therapy is effective in reducing recurrence of breast cancer and improving survival rates, it causes a number of side-effects, which impact on both quality of life and treatment adherence (Banning, 2012; Cella & Fallowfield, 2008). These side-effects vary in intensity and differ according to the treatments used and the extent to which they are tolerated by the individuals (Pinder & Buzdar, 2008). Most commonly reported side-effects include: musculoskeletal (pain and stiffness in joints; bone loss and osteoporosis), formation of blood clots (thromboembolism), cerebrovascular events, fluid retention, hot flushes, cognitive decline, alteration in weight, appetite, nausea, breast sensitivity, and depression (Banning, 2012; Cella & Fallowfield, 2008). Perhaps the most disturbing side-effect of hormonal treatment involves genitourinary atrophy, which impacts on vaginal (e.g. dryness, discharge, bleeding) and sexual functioning (Banning, 2012).

Overall, the treatments, although effective in reducing risk of breast cancer recurrence or prolonging remission, may have significant effects on quality of life, in particular sexual functioning. This issue will be explored further below.

1.4 Breast Cancer and Sexual Functioning

With decreasing breast cancer mortality and increasing survival rates, over the past thirty years there has been a growing interest in women's quality of life (Chevray & Robb, 2008; Den Oudsten, Van Heck, Van der Steeg, Roukema, & De Vries, 2009; Moons, Budts, & DeGeest, 2006). Professional Australian organisations (The Royal Australian and New Zealand College of Radiologists, the Royal Australian College of General Practitioners, The Royal Australasian College of Physicians) have urged health professionals to consider, and address, patients' quality of life concerns (including sexuality) in their routine care (Cancer Australia, 2010).

While quality of life encompasses a number of domains, including physical, mental, social, economic, and spiritual, sexuality is regarded as an integral part of quality of life (Gao & Dizon, 2013) and a 'central aspect of being human' (World Health Organization, 2006, p.5) . According to the classic theory of human motivation, Abraham Maslow (1943) identified sexual activity as a basic human need, integral to love and connection with others.

In general, women diagnosed with breast cancer show continued interest in sexuality, irrespective of age, stage of illness or level of disability (Hughes, 2008). In some cases, sexuality and intimacy can help to minimise emotional distress associated with the cancer diagnosis, and may assist the individual in adjusting to their cancer experience (Sadovsky et al., 2010). On the other hand, sexual difficulties may lead to relationship and emotional problems, both of which may have an impact on coping with cancer and treatment (Taylor, Harley, Ziegler, Brown, & Velikova, 2011; Tierney, 2008). Therefore, maintaining sexual functioning may be considered as one of the signs of overall wellbeing and the ability to cope with cancer and treatment (Taylor et al., 2011).

1.5 Understanding Sexual Function and Dysfunction

Sexual functioning can be defined as a process of giving and receiving sexual pleasure, often in the context of interaction with a sexual partner (Byers & Rehman, 2014). It may include various aspects of sexual activity, such as fantasy, hugging, touching, kissing, masturbation, oral genital stimulation and intercourse (Rissel et al., 2014; Tierney, 2008).

Considerable research has been conducted to define and formulate the nature of human sexual functioning. Initially, the formulation of the sexual response cycle was defined only in

men, which, over time, was refined and applied to both genders (Tierney, 2008). In the late 1960s, Masters and Johnson (1966) provided a formulation of the human sexual response cycle, consisting of stages that are experienced in a linear fashion: excitement, plateau, orgasm and resolution. Kaplan (1979) maintained this linear formulation and expanded it by including desire as the first stage of a three-stage model followed by excitement and orgasm. Zilbergeld and Ellison (1980) added the cognitive appraisal of the sexual encounter as the last stage of the response cycle.

Basson (2005) argued that sexual response cycles in males and females differ, and defined female sexual response as circular, rather than linear. The stages of female sexual response described include desire, arousal and satisfaction (with or without orgasm). Basson (2005) also reasoned that in females, sexual desire is likely to be less spontaneous than in males, as females tend to initiate and respond to sexual stimuli for a variety of reasons, some of which may not be sexual at all (e.g., increasing emotional intimacy; invoking a sense of feeling: attractive, feminine, appreciated, loved, desired; reducing anxiety or guilt about sexual infrequency).

Sexual dysfunction is defined as a disruption in one or more stages of the sexual response cycle (i.e., desire, arousal and orgasm), as well as the experience of pain during sexual activity, which results in significant levels of personal distress or disability (American Psychiatric Association, 2013; World Health Organization, 2004). The level of distress and impact on functioning is crucial in distinguishing between sexual complaint and dysfunction (American Psychiatric Association, 2013). The Diagnostic and Statistical Manual for Mental Disorders, Fifth Edition – DSM-5 (American Psychiatric Association, 2013), defines three sexual functioning disorders: Female Sexual Arousal Disorder, Female Orgasmic Disorder and Genito-Pelvic Pain/Penetration Disorder (see Table 1.1). For the diagnosis to be made, sexual difficulties cannot be better explained by other physical and mental disorders, and substance effects (American Psychiatric Association, 2013). DSM-5 acknowledges the significant comorbidities that exist amongst sexual functioning disorders as it is common for women to be diagnosed with more than one disorder (American Psychiatric Association, 2013).

Table 1.1: Symptoms of female sexual dysfunctions in DSM-5 (American Psychiatric Association, 2013)

Disorder	Symptoms
Female Sexual Interest / Arousal Disorder*	At least three of the following features being absent or significantly reduced: • Interest in sexual activity, • Erotic thoughts and fantasies, • Initiation of sexual activity, • Responsiveness to partner's initiation of the sexual activity, • Sexual excitement and pleasure during sexual activity, • Interest or arousal to internal/external erotic cues, • Genital and non-genital sensations during sexual activity,
Female Orgasmic Disorder*	Delay, infrequency or absence of orgasm or marked reduction in orgasmic sensations, in the context of adequate stimulation
Genito-pelvic Pain/Penetration Disorder*	Difficulty having sexual intercourse due to experiencing pain or tension of the pelvic floor muscles or experiencing significant fear of pain or vaginal penetration

*Significant distress needs to be present in addition to symptoms to warrant a diagnosis

1.6 Sexual Dysfunction in Breast Cancer Patients

Prevalence rates of sexual dysfunction in women diagnosed with breast cancer vary. Inconsistencies in definitions (e.g. sexual complaints and problems vs. dysfunctions), measures and samples used (e.g., age, stage of disease and treatment) all contribute to this variability (Thors, Broeckel, & Jacobsen, 2001).

While still undergoing treatment for breast cancer, the majority of women (64%-70%) report experiencing some level of sexual functioning difficulties that is significant enough to bother them (Kedde, van de Wiel, Weijmar Schultz, & Wijsen, 2013; Panjari, Bell, & Davis, 2011). When considering specific areas of sexual functioning, a significant proportion of women report difficulties with lubrication (33%-45%), pain (30%), orgasm (23%-31%), and desire [23%-42%; (Burwell, Case, Kaelin, & Avis, 2006; Kedde et al., 2013)]. When compared to pre-cancer sexual functioning, the majority of women report marked reductions in frequency of sexual activity (77.9%), energy for having sex (76%), arousal (73.6%), feeling desirable (73.4%), interest in sex (71.4%), sexual pleasure (64.2%), satisfaction with sex (61.9%) and intimacy (60.4%) following cancer diagnosis and treatment (Burwell et al., 2006; Ussher, Perz, & Gilbert, 2012).

Although the percentage of women experiencing sexual functioning difficulties tends to diminish over time, 35.5% - 45% of women continue to report sexual dysfunction well after all treatments have been completed (Kedde et al., 2013; Pumo et al., 2012). The most commonly reported long-term difficulties include lack of sexual interest (35%), arousal (28%), lubrication (23%), orgasm (21%-22%) and experiencing significant pain during sexual activity (16%) (Broeckel, Thors, Jacobsen, Small, & Cox, 2002; Kedde et al., 2013). Even short-term disruptions in sexual functioning can create frustration and distress and add to the burden of

breast cancer, while more chronic problems can impact on a woman's mental health and her relationships, as well as to serve as a reminder of her cancer history (Arrington, Cofrancesco, & Wu, 2004; Jeffery et al., 2009).

Sexual concerns can arise in all stages of breast cancer diagnosis, treatment and survivorship (Sadovsky et al., 2010). Aetiology of sexual dysfunction in these women may be caused by: (1) the cancer itself; (2) psychological distress associated with diagnosis of cancer; (3) the treatment of cancer and its side-effects; (4) psychological distress following treatment; and, (5) alterations in intimate relationships during and following treatment (Tierney, 2008). Biopsychosocial models have been proposed as frameworks for understanding how breast cancer and its treatment affect sexual functioning (Ganz, Desmond, Belin, Meyerowitz, & Rowlan, 1999; Tierney, 2008).

1.6.1 Biological factors affecting sexual functioning in breast cancer patients

Biological factors affecting sexual functioning in women with breast cancer include age (Bober & Varela, 2012; Bredart et al., 2011; Christie, Meyerowitz, & Maly, 2010; Den Oudsten, Van Heck, Van der Steeg, Roukema, & De Vries, 2010; Kinsinger, Laurenceau, Carver, & Antoni, 2011), menopausal status (Emilee, Ussher, & Perz, 2010) and the effects of the cancer itself as well that of treatment (Tierney, 2008).

There is little research on how the breast cancer itself may contribute to sexual dysfunction. Cancer-related changes in the hormonal milieu of a women's body may impact sexual functioning; however, empirical data to support this are needed (Tierney, 2008). Considerably more research is available on the effects of different breast cancer treatments on sexual functioning.

Surgical treatment, which typically involves removal of a part or the whole breast, often leaves scars that are permanent reminders of cancer, as well as the need to remain vigilant about possible recurrence (Ofman, 2004). Lymph node dissection along with radiation to the axilla also places a woman at increased risk of developing lymphoedema, which is characterized by excessive, highly visible swelling and pain, which usually affects the arm, and sometimes chest (Lawenda, Mondry, & Johnstone, 2009; Soran et al., 2014). This incurable condition may cause considerable diminution of physical and psychological functioning, overall quality of life, and challenge a woman's self-identity due to the highly visible changes to her physical appearance (Taghian, Miller, Jammallo, O'Toole, & Skolny, 2014). There is emerging evidence that lymphoedema negatively impacts on a woman's sexual functioning (Fu et al., 2013; Ridner, 2009; Winch et al., 2015).

As breasts are seen as a symbol of sexuality and femininity in Western cultures, removal of the breast tissue and resulting scars and disfigurement, may lead to a loss of sexual self-image and changes in sexual identity (Mercadante, Vitrano, & Catania, 2010; Sadovsky et al., 2010). Additionally, breast surgery may impact on a woman's breast and nipple sensitivity, which may affect her sexual arousal, especially if having her breasts touched was previously arousing (Mercadante et al., 2010; Sadovsky et al., 2010).

The evidence base is divided in relation to the effects of the type of surgical treatment on sexual functioning in women with breast cancer. Mastectomy has generally been found to be associated with more sexual functioning problems (Andrzejczak, Markocka-Maczka, & Lewandowski, 2013; Avis, Crawford, & Manuel, 2004; Karabulut & Erci, 2009) and poorer sexual adjustment (Kinsinger et al., 2011; Markopoulos et al., 2009) than breast conserving therapy. Additionally, in individuals who have undergone mastectomy, better sexual functioning has been found in women who undergo breast reconstructive surgery, following mastectomy (Manganiello, Hoga, Reberte, Miranda, & Rocha, 2011; Markopoulos et al., 2009). On the other hand, some researchers report no associations between surgery type and sexual functioning (Lam et al., 2012; Monteiro-Grillo, Marques-Vidal, & Jorge, 2005). Furthermore, sexual problems do not appear to influence the decision as to whether a women with mastectomy will undergo reconstructive surgery (Panjari et al., 2011).

Radiation Therapy often results in fatigue and general malaise, which can affect sexual desire - both spontaneous and responsive (Hughes, 2008; Mercadante et al., 2010; Sadovsky et al., 2010). Additionally, the skin changes caused may reduce sexual sensitivity of the treated area (Sadovsky et al., 2010). Permanent tattoos that are used to increase the precision of radiation treatment, can serve as constant reminders of the illness and its treatment (Ofman, 2004). Some women have reported avoiding physical contact while receiving radiation therapy for fear of contaminating their partner with radiation (Ofman, 2004).

Chemotherapy also has a number of side effects that may directly or indirectly affect sexual functioning in women with breast cancer. Loss of sexual feeling has been rated as the sixth most severe side-effect of chemotherapy (Carelle et al., 2002), with fatigue, nausea and weakness, impacting on sexual desire and frequency of intercourse (Hughes, 2008; Mercadante et al., 2010). Alopecia (i.e., hair loss), may also lead to reduction in a woman's body image and her sexual self-esteem, given the strong emphasis that Western society places on physical appearance (Hughes, 2008).

Chemotherapy can also affect gonadal function and cause menopause in pre-menopausal women, which may have adverse effects on sexual functioning (Hughes, 2008). The loss of

oestrogen (resulting from chemotherapy) can cause shrinking, thinning, and loss of elasticity of the vagina, and vaginal dryness, all of which have a direct effect on sexual functioning and pleasure (Mercadante et al., 2010). Additionally, due to loss of normal ovarian function, the vaginal eco system may change, leading to increased frequency of urinary tract infections, which may also impede sexual activity (Keeler, Ramirez, & Freedman, 2008). Lastly, the common side-effect of chemotherapy-induced neuropathy, which often affect the hands and feet, can sometimes affect the clitoris, reducing sexual arousal and pleasure (Hughes, 2008).

Generally, women with a history of chemotherapy tend to report worse sexual functioning (Alder et al., 2008; Beckjord & Campas, 2007; Berglund, Nystedt, Bolund, Sjoden, & Rutquist, 2001). Additionally, women with chemically-induced menopause tend to report worse sexual functioning than those treated with chemotherapy who were still menstruating post-treatment (Bober & Varela, 2012; Ochsenkuhn et al., 2011). However, in a longitudinal study by Den Oudsten et al. (2010) found that whether women received chemotherapy was not predictive of sexual functioning six and twelve months after diagnosis.

Hormone therapies have a differential impact on sexual functioning depending on the agents used, as they have different profiles of side-effects. Tamoxifen, which may be given to both premenopausal and postmenopausal women who have oestrogen receptor positive breast cancer, can cause hot flushes, joint pains, headaches, vaginal atrophic changes (e.g. dryness, itching and discharge), insomnia and mood disturbances (Knobf, 2006; Mourtis et al., 2001). These side-effects of Tamoxifen may be more pronounced in younger, pre-menopausal women (Mourtis et al., 2001). Aromatase inhibitors, given to oestrogen receptor positive postmenopausal women, may cause hot flushes, vaginal dryness, bleeding and discharge, sleeping difficulties, fatigue, musculoskeletal complaints, headache, decreased libido and breast tenderness (Knobf, 2006).

The evidence base is inconclusive about the effects of hormone therapy (and different agents) on sexual functioning in women with breast cancer, possibly due to poor study design (Mok, Juraskova, & Friedlander, 2008), and difficulty in separating the effects of hormone treatments from other treatments women typically receive prior to commencing hormone therapy (i.e., surgery, radiation therapy and chemotherapy).

In a preliminary study Martimer et al. (1999) concluded that Tamoxifen results in an increase in vaginal symptoms, which leads to dysfunction, especially dyspareunia. However, Berglund et al. (2001) found that the negative effect of Tamoxifen on sexual functioning is only apparent in women who have not received chemotherapy. Additionally, this effect was found to decrease after the treatment was completed, although given that most women take hormonal therapies for at least five years, this finding has less significance. Lastly, Frechette et al. (2013) found that, for

postmenopausal women, sexual functioning after six months of hormone treatment did not differ to baseline (prior to commencement of Tamoxifen), which may be due to the general trend for post-menopausal women to have lower sexual functioning than pre-menopausal women (Kim et al., 2009).

In a review of the effect of Aromatase Inhibitors on sexual functioning, Mok et al. (2008) identified only five studies, all of which compared the effects of Aromatase Inhibitors to those of Tamoxifen. Generally, the evidence suggests that Aromatase Inhibitors result in more vaginal complaints (dryness and dyspareunia) than Tamoxifen or placebo. However, one study in this review showed that switching to Aromatase Inhibitors after two to three years of Tamoxifen appears to result in no more adverse effects on sexual functioning than using Tamoxifen for the duration of the treatment (Fallowfield et al., 2006). Kwan and Chlebowski (2009) recommended switching to Tamoxifen if vaginal complaints cannot be managed by non-hormone treatments.

1.6.2 Psychological factors affecting sexual functioning in breast cancer patients

Breast cancer diagnosis and treatment have been found to have a significant impact on a women's psychological wellbeing. The first year following cancer diagnosis is usually associated with considerable challenges for both the woman and her family (Knobf, 2007), with many viewing a breast cancer diagnosis a death sentence, despite the obvious improvements in treatment and long-term management of this condition (Ofman, 2004). During this time, a woman is required to make complex decisions regarding her treatment, which may lead to feelings of vulnerability, uncertainty, frustration, anger and disappointment (Hughes, 2008; Knobf, 2007). Additionally, she may face existential concerns regarding age-appropriate developmental goals, such as education, marriage, child rearing, pregnancy and retirement (Hughes, 2008; Knobf, 2007). Psychological distress, which is frequently reported by women diagnosed with breast cancer can arise from feelings of grief and loss (e.g., fertility, the breast), isolation, body image concerns, role adjustments, anxiety about economic concerns, cancer recurrence, treatment efficacy and side-effects, and concerns about handing down 'flawed' genetic material (Knobf, 2007; Ofman, 2004; Tierney, 2008). The guilt about lifestyle choices may also cause distress in some women, although no clear link has been found in the literature (Ofman, 2004). In general, psychological distress has been found to have a negative effect on sexual desire (Carey, 2006), while the perceived ability to cope is found to positively influence sexual functioning (Quintard, Constant, Lakdja, & Labeyrie-Lagardere, 2014).

Most women show a gradual improvement in psychological symptoms over the first six to twelve months; however, some women still experience significant distress well after the cancer

treatment is completed (Knobf, 2007). Similarly, while some women report experiencing personal growth and development following breast cancer, 20-30% of women continue to report symptoms of depression, anxiety and post-traumatic stress disorder (PTSD) beyond the first 12 months (Knobf, 2007; Schmid-Buchi, Halfens, Dassen, & van den Borne, 2011). Younger women, and those lacking adequate social support, with a prior history of psychosocial problems, and from cultural minorities are at a greater risk of developing significant psychological symptoms following breast cancer diagnosis and treatment (Knobf, 2007).

The research evidence suggests that in women with breast cancer, more severe symptoms of depression have been associated with sexual dysfunction, in particular, lower desire (Beckjord & Campas, 2007; Hughes, 2008; Speer et al., 2005). Furthermore, in the general population, the commonly prescribed medications for treatment of depression (selective serotonin reuptake inhibitors – SSRI) have been shown to cause sexual dysfunction in 20-40% of people, particularly decreased desire and lubrication (Clayton et al., 2002; Henson, 2002). In a longitudinal study of women diagnosed with breast cancer, Den Oudsten et al. (2010) demonstrated that trait anxiety predicts level of sexual functioning at 12 months post-surgery. General mental health, psychological distress and level of optimism have been shown to influence recovery from sexual difficulties resulting from breast cancer and treatment (Fobair et al., 2006; Lam et al., 2012; Manganiello et al., 2011; Wimberly, Carver, & Antoni, 2008).

Body image is seen as critical for sexual arousal and responsiveness (Henson, 2002), yet altered body image is commonly reported following breast cancer treatment (Helms, O'Hea, & Corso, 2008). Depression and anxiety may also distort a woman's view of herself and undermine her positive body image (Lam, Chan, Hung, Or, & Fielding, 2009; Rabinowitz, 2002). Women diagnosed with breast cancer who report poor body image are 2.5 times more likely to report sexual dysfunction than those reporting better body image (Panjari et al., 2011). Poor body image in breast cancer survivors has also been linked to decreased arousal and excitement in male partners (Henson, 2002).

Breast cancer treatments often result in significant fatigue, which is rated as one of the most distressing side-effects that often persists after treatment is completed and when the cancer is in remission (Berger, Gerber, & Mayer, 2012; Bower et al., 2006). Fatigue almost universally accompanies other clinical conditions, such as depression, anxiety and PTSD (Berger et al., 2012; Henson, 2002). Not surprisingly, increased fatigue has been related to sexual dysfunction (Den Oudsten et al., 2010; Henson, 2002). Distress associated with persistent fatigue has also been found to result in disruptions in desire (Tierney, 2008).

1.6.3 Social factors affecting sexual functioning in breast cancer patients

Social support plays a key role in how a person adjusts to a life crisis such as a breast cancer diagnosis (Kinsinger et al., 2011). It encompasses emotional, experiential and practical support provided by family, friends, and communities, as well as the oncology health care team (Knobf, 2011). In women with breast cancer, adequate social support has been associated with not only better coping and less psychological distress, but also better medical prognosis (Knobf, 2011). After completion of treatment, the need for professional support typically decreases, while the need for the family and informal supports remains high (Schmid-Buchi et al., 2011). However, some relatives report being negatively affected by observing a loved one cope with breast cancer and its sequelae, as well as experiencing an increased burden by placing themselves in a role of the 'carer' for a person with cancer (Schmid-Buchi et al., 2011).

Whereas both objective and perceived social supports are important determinants of the general physical and psychological well-being of a women diagnosed with breast cancer, the quality of her relationship with her intimate partner is one of the strongest predictors of sexual dysfunction in women diagnosed with breast cancer (Ganz et al., 1999; Kinsinger et al., 2011). The majority of women tend to experience greater closeness and increased intimacy with their partners after breast cancer (Walsh, Manuel, & Avis, 2005). Unfortunately, 25% of women experience their partners becoming emotionally unavailable and avoiding communication about emotional issues, in particular disease progression and sexuality (Walsh et al., 2005; Yu & Sherman, 2015). Some women reported that breast cancer diagnosis and treatment exacerbated relationship problems that were present prior to this crisis, with the conflict sometimes leading to relationship breakdown (Holmberg, Scott, Alexy, & Fife, 2001; Hughes, 2008; Walsh et al., 2005). Unpartnered women diagnosed with breast cancer tend to report more sadness, anger and hurt feelings, and less reliance on informal social supports (friends and family) and more reliance on formal social supports, such as support groups, than women with partners (Holmberg et al., 2001). Women without a partner at times report negative responses from their former partners regarding their physical appearance changes, which in turn leads to worry about similar comments from future partners (Holmberg et al., 2001). Additionally they may be concerned about the most appropriate time, and manner, of disclosing information about their breast cancer diagnosis and associated altered appearance (Holmberg et al., 2001).

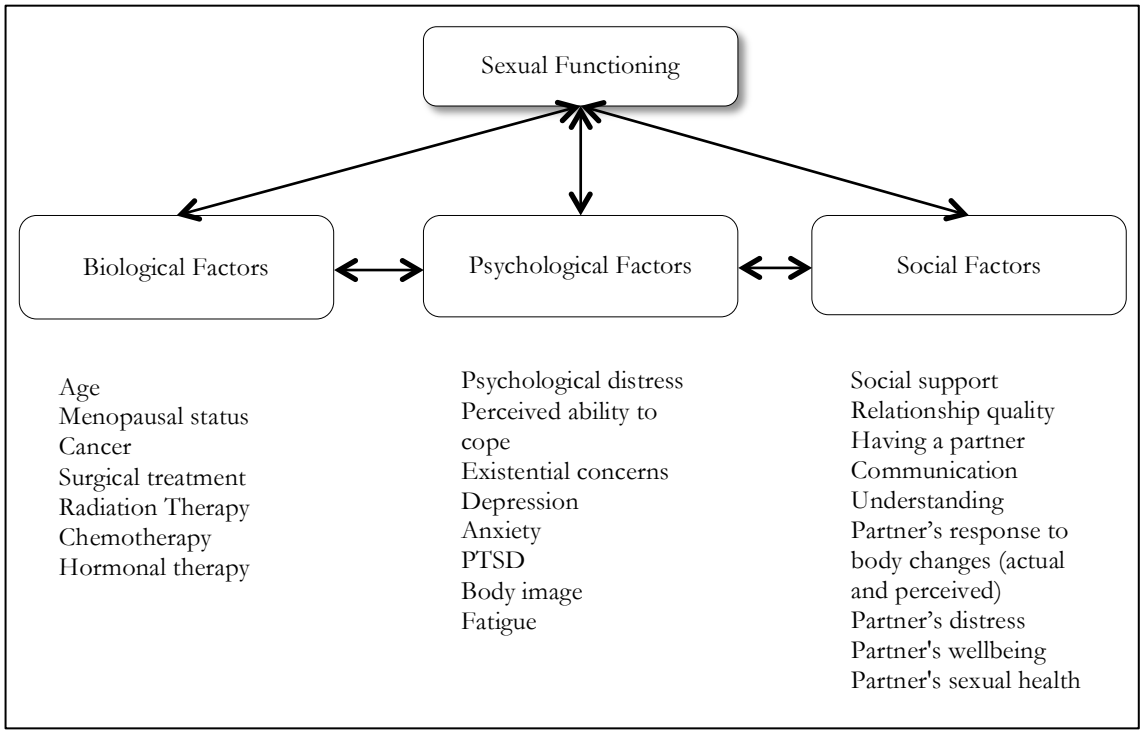
In intimate relationships, perceived emotional, instrumental and informational support is related to sexual functioning with the potential to 'buffer' against negative effects of cancer and its treatment (Kinsinger et al., 2011). Women tend to report an increase in instrumental support following diagnosis and treatment of breast cancer (Holmberg et al., 2001). The perceived level

of the partner's emotional involvement, the frequency of sex, the frequency of a partner initiating sexual activity and the perceived partner's reactions to the scar, all influence sexual adjustment (Wimberly, Carver, Laurenceau, Harris, & Antoni, 2005). The ease of discussing sexual changes with one's partner, along with the partner's level of understanding of the woman's feelings have also been shown to be important determinants of sexual functioning (Fobair et al., 2006; Hughes, 2008; Pelusi, 2006).

Breast cancer and its treatment also tend to significantly impact partners who frequently experience anxiety about the potential death of their intimate partner, and avoid communicating these concerns so as not to further distress the affected woman (Holmberg et al., 2001). Consequently, many male partners report diminished desire in the initial months following the breast cancer diagnosis and treatment (Holmberg et al., 2001). While some partners report that the changes in the woman's appearance are not as important as survival and general wellbeing (Holmberg et al., 2001), others find these changes unattractive and less feminine, resulting in the loss of sexual desire (Rowland & Metcalfe, 2014; Tierney, 2008). Some men avoid touching the scars as they find them unappealing or they fear hurting their partner (Rowland & Metcalfe, 2014; Sandham & Harcourt, 2007). Some men feel relieved when their partner covers the scars (Rowland & Metcalfe, 2014). Not surprisingly, many men also report a decline in sexual functioning, some of which is related to the way they perceive their sexual partner post-breast cancer treatment (Rowland & Metcalfe, 2014). Additionally, some men may withdraw from initiating sexual activity in response to their perceptions of their partner's depression, anxiety, altered body image and loss of confidence (Wimberly et al., 2005). Lastly, the partner's general and sexual health has a significant impact on the couple's sexual functioning (Pelusi, 2006).

Clearly, there are a multitude of factors affecting a woman's sexual functioning post-breast cancer diagnosis and treatment. These factors are summarised in Figure 1.1, which was adapted from Tierney (2008).

Figure 1.1: Biopsychosocial model of sexual dysfunction in women with breast cancer



1.7 Treatments for Sexual Dysfunction in Breast Cancer

The following section provides an overview of the intervention approaches that have been applied to address sexual dysfunction in women diagnosed with breast cancer. As sexual dysfunction is affected by bio-psycho-social factors, Bober and Varela (2012) have urged clinicians and researchers to use integrative interventions.

1.7.1 Biological treatments for sexual dysfunction following breast cancer

Biological interventions usually focus on managing side effects of the breast cancer treatments (e.g. menopausal symptoms) and directly targeting sexual dysfunction.

Pharmacological treatment of hot flushes with antidepressants (serotonin-norepinephrine inhibitor – SNRI) and antihypertension drugs may lead to improvements in sexual functioning (Hahn, 2008; Taylor et al., 2011). The use of hormone replacement therapy (using systemic oestrogen) to manage menopausal symptoms has not been recommended for breast cancer patients as it increases the risk of breast cancer recurrence; however, low dose, vaginal oestrogen therapy can be considered in patients who did not respond to other non-hormone treatments (Derzko, Elliott, & Lam, 2007; Trinkaus, Chin, Wolfman, Simmons, & Clemons, 2008).

There is limited evidence for using pharmacological treatments for sexual dysfunction in women with breast cancer (Bober & Varela, 2012). There is some evidence that testosterone

treatments (together with oestrogen therapy) may be helpful in alleviating reduction in sexual desire in postmenopausal women without a history of breast cancer, the evidence for efficacy and safety of testosterone treatments alone is lacking and thus is not recommended for women with breast cancer (Derzko et al., 2007; Hahn, 2008). There is some preliminary data indicating the usefulness and safety of topical testosterone in women with breast cancer (Witherby et al., 2011), but more thorough research is needed. Sildenafil (Viagra) and Alprostadil can be helpful in producing vaginal physiological changes that may lead to increased subjective arousal, ability to achieve orgasm and increase in overall satisfaction in some post-menopausal women (Derzko et al., 2007; Hahn, 2008). However, data about efficacy and safety of these treatments in breast cancer patients is lacking.

Many women with breast cancer benefit from using water-soluble vaginal lubricants (e.g., KY Jelly and Astroglide) for comfort during sexual activity (Derzko et al., 2007; Hahn, 2008). Vaginal moisturizers (e.g. Replens) that are sometimes prescribed for vaginal atrophy following breast cancer treatment can provide temporary relief; however, the effects are not maintained after use is discontinued (Biglia et al., 2010). In a preliminary study in intervention for dyspareunia following breast cancer treatment, the use of vaginal lubricant (olive oil, used during intercourse), vaginal moisturizer (Replens, used three times a week) and vaginal exercises (twice a day) were found to be well tolerated, safe and effective (Juraskova et al., 2013).

1.7.2 Psychological treatments for sexual dysfunction following breast cancer

Psychological interventions generally focus on treating psychological distress and mental health concerns that often affect sexual functioning, and treating sexual dysfunction directly.

Exercise aimed at improving general well-being and body image has produced limited effects on sexual functioning (Taylor et al., 2011). There are some studies providing evidence for the effectiveness of psychotherapy in improving sexual functioning in women with breast cancer (Derzko et al., 2007; Hahn, 2008; Krychman & Katz, 2012; Taylor et al., 2011). Telephone and face-to-face therapies have been found to be effective in improving sexual functioning (Taylor et al., 2011), and generally, counselling provided by professionals (rather than peers) and involving the partner have been found to be most effective (Krychman & Katz, 2012; Taylor et al., 2011). There is some evidence to suggest that there is a dose-response effect, with more sessions resulting in better outcomes (Krychman & Katz, 2012; Taylor et al., 2011).

Psychotherapy in studies showing effectiveness in increasing sexual functioning in women with breast cancer has had a number of different components including: providing the couple with education regarding cancer diagnosis and treatment (including the effects on sexual

functioning); general coping and problem-solving strategies; specific sex therapy strategies (e.g. sensate focus); graded exposure to the mastectomy scar (for both women and their partners); general relationship enhancement strategies (couple problem-solving, emotional expressiveness, post-traumatic growth etc.); and, cognitive behavioural strategies to address mood disturbance, body image and sexual dysfunction (Duijts et al., 2012; Krychman & Katz, 2012; Taylor et al., 2011).

Mindfulness practice can be helpful in getting women and their partners to increase their ability to attend to physical sensations during sexual activity and to avoid distractions. Mindfulness has been helpful in reducing women's distress, anxiety, depression, fatigue and improving sleep (Krychman & Katz, 2012). Recently, Oh et al. (2014) in their preliminary study found that ten group-based Qigong and meditation sessions were feasible, well received and resulted in a non-significant trend towards better sexual functioning in women with metastatic breast cancer. Therefore, more research in this area is needed.

1.7.3 Implementation of treatments to improve sexual functioning

In general, women with breast cancer tend to have multidisciplinary treating teams, with various degrees of knowledge, skills, experience and comfort in discussing sexual difficulties. Annon's (1976) PLISSIT model (P- Permission, LI – Limited Information, SS – Specific Suggestions, IT – Intensive Therapy) is a useful framework that was developed for formulating treatment of sexual dysfunction. It has been recommended for implementation in the breast cancer context (Kinamore, 2008; Pillai-Friedman & Ashline, 2014).

PLISSIT consists of four levels of intervention for addressing sexual difficulties, depending on the severity of the problem (Pillai-Friedman & Ashline, 2014), and each different level requires increasing amount of expertise in treating sexual difficulties (Kinamore, 2008). The first level – P (Permission), requires health professionals to give permission to the breast cancer patients and their partners to talk about sexual concerns during consultations. The second level, LI (Limited Information) requires provision of information about breast cancer, and its treatment and effects on sexual functioning through brochures, booklets, electronic resources and information seminars (Pillai-Friedman & Ashline, 2014). The third level, SS (Specific Suggestions) requires professionals to provide strategies to breast cancer patients that are specific to improving sexual adjustment, for example, the use of vaginal moisturizers and lubricants and advice on sexual positioning (Pillai-Friedman & Ashline, 2014). Women may experience improvement in sexual functioning through receiving intervention at the P, LI or SS levels. Some women, however, require more Intensive Therapy (IT; fourth level of the intervention

model), which is often due to the complexity of issues that they are facing that may influence sexual functioning, such as mental health problems, relationship difficulties, grief and loss, trauma and poor coping with cancer and treatment (Pillai-Friedman & Ashline, 2014).

All professionals working in oncology should have the skills and experience to grant permission for sexuality to be discussed – P (Dean, 2008; Pillai-Friedman & Ashline, 2014). Levels two and three (LI, SS) constitute short-term intervention (Annon, 1976) and can be performed by people on the treatment team who have experience and skills in providing information and strategies regarding sexual functioning to people with breast cancer (Pillai-Friedman & Ashline, 2014). Level 4 intervention (IT) may require a referral to an appropriately trained psychologist, psychotherapist or sex therapist (Dean, 2008; Pillai-Friedman & Ashline, 2014).

1.8 Difficulty Initiating Conversations About Sex

Although the first stage of the PLISSIT model is providing permission to discuss sexual functioning, the evidence suggests that sexuality is not routinely discussed and not discussed in sufficient detail (Bober & Varela, 2012; Tierney, 2008). Only a third of patients have reported ever discussing their sexual concerns with health professionals, of which just 37% were satisfied with the outcome (Hawkins et al., 2009).

When faced with a life-threatening disease, women with breast cancer may feel that their sexual functioning is not as important as medical issues (Derzko et al., 2007). Additionally, women may not be aware that their sexual difficulties may be related to the cancer and its treatment, as they may believe that oncology professionals would have raised the issue if it were the case (Ofman, 2004). Typically, the women tend to wait for the topic to be raised by health professionals (Moreira et al., 2005), hence, it is crucial that oncology professionals initiate conversations about sexuality (P – Permission), as it demonstrates to the patients that talking about sexual functioning is important (Hahn, 2008).

Numerous barriers to professionals initiating conversations about sexual functioning have been found in the literature. There may be a lack of privacy in hospital settings, which may hinder openly discussing these matters (Hughes, 2008). Additionally, time constraints, as well as lack of resources to treat significant issues have been noted as barriers to open communication about sex (Taylor et al., 2011). Internationally, the word 'vagina' is associated with a large number of derogatory terms, making it harder to discuss anything associated with it for women with breast cancer and health professionals alike (Nappi, Liekens, & Brandenburg, 2006). Thus, health professionals may feel it is inappropriate to discuss sexual functioning as they may see it as

disrespectful in relation to the woman's age, religion, culture and socio-economic status (Ofman, 2004; Taylor et al., 2011). Moreover, health professionals sometimes falsely assume that sexuality is not important for women with advanced disease and in palliative care (Mercadante et al., 2010). They may be worried about not having adequate skills to treat sexual difficulties in breast cancer patients and over-involvement in non-medical issues, as they often receive limited training in this area (Bober & Varela, 2012; Hordem & Street, 2007).

All of the factors above lead to 'structured silence' in which both women with breast cancer and health practitioners are reluctant to discuss changes in sexual functioning difficulties, which may prevent accessing appropriate support (Knobf, 2011).

1.9 The Importance of Sexual Dysfunction Scales

Sexual functioning assessments can be conducted in a number of ways: clinical interviews (including structured interviews), self-report scales (questionnaires), physical examinations and hormonal evaluations (Derzko et al., 2007). The focus of the present thesis is on the use of self-report scales as they are: (1) relatively short, which is important given time constrains in clinical practice; (2) require few resources to administer, score and interpret; and, (3) can be administered by a wide range of professionals, as they require little additional training. The latter is important, as the oncology treating team is often multidisciplinary, with varied levels of expertise in sexuality and psychometric theory.

In clinical practice, the 'structured silence' that is often experienced between patients and practitioners prevents women with sexual functioning concerns from having these concerns identified and treated (Knobf, 2011), preventing the activation of any of the PLISSIT levels of intervention. A sexual dysfunction scale that is routinely administered at various stages of breast cancer treatment would allow for the identification of sexual concerns in these women, and could be used to inform the appropriate treatment level, according to the PLISSIT model. Additionally, this assessment could act as a 'conversation starter' between patients and professionals to overcome some of the barriers to open communication noted above.

As psychological interventions produce better outcomes when they target specific sexual problems, the results from a sexual dysfunction scale would prove invaluable to understanding exactly where the difficulties lie (Taylor et al., 2011). Additionally, as pre-cancer level of sexual functioning has been found to be predictive of sexual dysfunction following diagnosis and treatment, measuring sexual difficulties prior to commencement of treatment is important in treatment planning (Ofman, 2004). Lastly, sexual dysfunction scales would be helpful in documenting changes in sexual functioning that may result from any intervention applied.

When conducting breast cancer research, sexual dysfunction scales are necessary for documenting altered sexual functioning that is related to breast cancer treatment. Therefore, routinely administering such measures at various stages of the treatment would help increase understanding of sexual side effects of breast cancer treatments. Providing this information to women and their partners may help decide between various treatment options. Given the considerable evidence base supporting the variety of biological and psychological interventions for sexual functioning, an appropriate sexual dysfunction scale is essential for documenting changes in sexual functioning that may be due to interventions and in being able to track sexual functioning changes in these cancer populations for research purposes.

1.10 Objective and Outline of the Thesis

The overall objective of this thesis is to identify a scale screening for sexual dysfunction that is:

- Simple enough to be routinely administered to women with breast cancer by a variety of health professionals
- Seen as acceptable to women with breast cancer
- Has adequate psychometric properties for use in the breast cancer population.

As the first step, a systematic review of literature of all sexual dysfunction scales that have been used in breast cancer research was conducted to identify the scales that have most favourable psychometric properties (Chapter 2). As the focus was on identifying women who are experiencing sexual dysfunction, the extent to which the existing scales cover the areas of sexual dysfunction as listed in international classification systems (American Psychiatric Association, 2013; World Health Organization, 2004) was also assessed in this review. This is the first review that has focused on breast cancer specifically, and it extended the previous knowledge of sexual dysfunction scales in oncology (Cull, 1992; Jeffery et al., 2009; Lorenz, Stephenson, & Meston, 2011). Such a review provides a useful summary of literature that both clinicians and researchers can use to decide on an appropriate scale to implement in their practice. This review identified the Female Sexual Function Index – FSFI (Rosen et al., 2000) as a promising measure.

The first empirical study investigated the acceptability and psychometric properties of the FSFI with women diagnosed with breast cancer (Chapter 3). The second empirical study (Chapter 4) reported on the development and validation of the breast cancer adaptation of the FSFI (FSFI-BC) that was created to address the shortcomings of the FSFI, as highlighted in the first empirical study. The final chapter (Chapter 5) aimed to integrate all of the findings of the

thesis and provide clinical implications of the results, together with the recommendations for future research.

'Screening for Sexual Dysfunction in Women Diagnosed with Breast Cancer: Systematic Review and Recommendations'

As discussed in Chapter 1, an appropriate scale suitable for screening for sexual dysfunction in women with breast cancer would be beneficial for both clinical practice and research. In clinical practice, routine use of such a scale would lead to identification of women that are in need of intervention for sexual difficulties. In research settings this scale could be used to monitor the side effects that treatments may have on sexual functioning. In both clinical practice and research, an appropriate scale screening for sexual dysfunction could be used to monitor the effects of any interventions used to treat sexual difficulties and dysfunction.

Unfortunately, there is no 'gold standard' measure that has been identified for this purpose. In fact, numerous scales have been used in research to report on sexual functioning of women with breast cancer, which makes it difficult for both clinicians and researchers to decide on the most appropriate scale to use.

The systematic review presented in this chapter aims at synthesising psychometric evidence for the 30 sexual functioning scales that have been used in breast cancer research from 1992 - 2013. To make the review practical and understandable for a variety of practitioners, regardless of their familiarity with psychometric and sexual dysfunction theories, each scale evaluated was assigned a score representing the quality of psychometric evidence as well as the degree to which the questions covered the aspects of sexual dysfunction.

This systematic review was published in Breast Cancer Research and Treatment:

Bartula, I., & Sherman, K. A. (2013). Screening for sexual dysfunction in women diagnosed with breast cancer: systematic review and recommendations. *Breast Cancer Research and Treatment, 141*(2), 173-185. doi: 10.1007/s10549-013-2685-9

Additionally, material from this systematic review was presented at the Australasian Society for Behavioural Health and Medicine 11th Annual Scientific Meeting in Auckland on 12th February 2014 (please see Appendix II for presentation)

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REVIEW

Screening for sexual dysfunction in women diagnosed with breast cancer: systematic review and recommendations

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Abstract Breast cancer patients are at increased risk of sexual dysfunction. Despite this, both patients and practitioners are reluctant to initiate a conversation about sexuality. A sexual dysfunction screening tool would be helpful in clinical practice and research, however, no scale has yet been identified as a "gold standard" for this purpose. The present review aimed at evaluating the scales used in breast cancer research in respect to their psychometric properties and the extent to which they measure the DSM-5/ICD-10 aspects of sexual dysfunction. A comprehensive search of the literature was conducted for the period 1992–2013, yielding 129 studies using 30 different scales measuring sexual functioning, that were evaluated in the present review. Three scales (Arizona Sexual Experience Scale, Female Sexual Functioning Index, and Sexual Problems Scale) were identified as most closely meeting criteria for acceptable psychometric properties and incorporation of the DSM-5/ICD-10 areas of sexual dysfunction. Clinical implications for implementation of these measures are discussed as well as directions for further research.

Keywords Breast neoplasms · Sexual dysfunction · Psychological · Psychometrics · Questionnaires · DSM-5 · ICD-10

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Introduction

Breast cancer is the second most common cancer worldwide and the most commonly diagnosed female cancer [1]. With high 5-year survival rates (76–92 %) there are increasing numbers of breast cancer survivors [2], leading to a focus on aspects of quality of life (QOL) [3], due to the long-term effects of cancer and its treatment [4, 5]. Most women (50–75 %) diagnosed with breast cancer report persistent difficulties with sexual functioning [6–8]. Biological, psychological, and social factors all contribute to the development of this sexual dysfunction [9]. Neglecting to address these issues may contribute to further distress and relationship difficulties, and possibly impact other aspects of women's lives [10].

Sexual assessment and counseling are not routinely provided in oncological settings [11], with less than one-third of breast cancer patients reporting having discussed sexuality concerns with a healthcare professional [12], of these few report satisfaction with the consultation [12], and generally these discussions only occur if the medical practitioner raises the subject [13]. Practitioners' reluctance to initiate these conversations may stem from fears of litigation and over-involvement in non-medical issues, embarrassment, and misleading assumptions held about their patients' priorities for treatment [14].

Considering the barriers to discussing these issues, an easily administered, reliable, and valid scale measuring sexual functioning may be useful as a screening tool and to help facilitate clinic-based conversations. In research, such a scale may be used to quantify treatment outcomes and side effects. It is important that any such measure incorporates all dimensions of sexual dysfunction, as defined by internationally accepted diagnostic criteria, Diagnostic and Statistical Manual of Mental Disorders, DSM-5 [15] and

International Classification of Diseases and Related Health Problems, ICD-10 [16]. These dimensions include desire to have sexual activity, excitement/arousal, orgasm, pain, and distress/dysfunction.

To date, there have been three published reviews of scales measuring sexual functioning in individuals with cancer [10, 17, 18], none of which specifically focused on breast cancer, which requires separate consideration because (1) breasts are considered symbols of sexuality and feminism in Western cultures, which may lead to adverse impact of breast cancer and treatment on women's feminine and sexual identity [19]; (2) women report reduced sexual arousal from breast stimulation following breast surgery [20]; and (3) women may experience diminished sexual responsiveness due to hormonal treatments used for managing breast cancer [21].

Prior reviews are also limited in that they: do not reflect current research in this area [17]; reviewed a select number of measures [18]; focused on measures used in all cancers, rather than breast cancer specifically [10, 17, 18]; and, neglected to include sexual functioning subscales incorporated within QOL measures [10, 17, 18], which are often used in treatment outcomes research. Additionally, no reviews have delineated the extent to which the scales incorporate the DSM-5/ICD-10 dimensions of sexual dysfunction.

Unfortunately very few scales used in breast cancer research have actually been *validated* on this population. For this reason, our review will delineate the psychometric properties of scales *applied* within this context. Only self-report measures were considered since they are easy to administer, relatively cost-effective, and may be less intrusive than other modes of assessment [22]. The specific aims were to: (1) evaluate the psychometric properties of available measures; and (2) evaluate the extent to which these measures incorporate DSM-5/ICD-10 sexual dysfunction criteria. The psychometric properties reviewed included reliability, validity and responsiveness to change. The definitions of these terms, methods of measurement and psychometric evaluation criteria are presented in Table 1. As sexual dysfunction is a sensitive subject, the patients' acceptability of scale questions was also evaluated.

Materials and methods

Search strategy

Literature searching using CINAHL, Embase, MEDLINE, PsycINFO, PubMed from 1992 to 2013 was conducted using the terms "breast cancer," "breast neoplasms", "sexual functioning," and "sexual dysfunction." The search was limited to empirical studies published in English language peer-reviewed journals.

Inclusion and exclusion criteria

The review inclusion and exclusion criteria are listed in Table 2. Where the title or abstract indicated that exclusion criteria were met, the study was rejected. Full text articles were accessed when: (1) it was not clear from the title or abstract whether the inclusion criteria were met or what sexual functioning scale was used; and, (2) inclusion criteria were met and the empirical studies for scales were reviewed.

Scale evaluation scoring system

Each included scale was assessed using the following criteria: (1) psychometric properties; and (2) coverage of DSM-5/ICD-10 dimensions of sexual dysfunction [15, 16]. A score was assigned to each scale indicating the extent to which it had adequate psychometric properties and covered the dimensions of sexual dysfunction (see Table 1 for scoring system). Additional points were awarded based on the characteristics of the validation sample, where "1" was given to studies where $n > 300$, as this is recommended for scale validation [23], and "0.5" where sample sizes were between 200 and 299. Since scale psychometric properties are dependent on the population studied [24], "1" was given if the validation sample included women with breast cancer, and "0.5" if it included cancer patients generally. Scores for the extent to which the DSM-5/ICD-10 dimensions of sexual dysfunction were incorporated were: "1" for each time at least one question covered one of the five domains (Desire, Arousal, Orgasm, Pain, Distress), with a maximum score of 5. Scores for all quality criteria were summed, with a maximum score of 17 (i.e., 12 psychometric property points and 5 for DSM-5/ICD-10 criteria). The first author (IB) rated the measures first, followed by the second author (KS). Any disagreements were discussed until an agreement was reached.

Results

Literature search results

The literature search results are presented in Fig. 1. Out of the 2,192 citations initially identified, 129 studies met the inclusion criteria, using 30 different scales, 18 of which were specifically designed to measure sexual functioning, and 12 were subscales within QOL questionnaires. For the latter, only psychometric properties for sexual functioning subscales were reviewed.

Evaluation of sexual functioning scales

The evaluation of the sexual functioning scales is presented in Tables 3 and 4. Where multiple validation studies for the

Table 1 Psychometric properties of scales and scoring rules for evaluation

Psychometric property	Definition	Method of measurement	Psychometric evaluation criteria	Scoring
Reliability				
Internal consistency	Extent to which all scale items are measuring the same construct	Cronbach's α	0.70–0.90 [24, 46]	"1": ≥0.7 "0": <0.7
		Item total correlation	≥0.40 [47]	"1": ≥0.40 "0": <0.40
Test–retest reliability	Degree of consistency in scores obtained by the same people on two different occasions, assuming no real change in the construct has occurred	Correlation coefficient between scores obtained on two occasions some time apart (maximum 2–4 weeks)	≥0.70 [46, 48]	"1": ≥0.7 "0": <0.7
Validity				
Content	Extent to which items in a scale cover the construct adequately	Based on theory, existing scales, expert opinion and clinical observation, qualitative feedback from professionals, researchers and participants	N/A	"1": evidence of the measure being based on theory, literature review, or examined by patients, professionals and experts in the field
Criterion	How well the scale relates to the "true value" or a "gold standard" for measuring the construct	Correlation coefficient between survey and criterion scores	The higher the correlation the more valid the instrument. Acceptable values include significant moderate ($r > 0.30$) to high ($r > 0.50$) correlations [48–51]	"0.5" if correlation coefficient is between 0.30 and 0.49 and "1" if the correlation coefficient is above 0.50 between the scale and the "gold standard" measure either taken at the same time (*concurrent*) or in the future (*predictive*)
Construct	Extent to which hypothesized relationships with similar (*convergent*) or different (*discriminant*) constructs are confirmed	Correlation coefficient between survey scores and hypothesized variables	Moderate correlations with similar constructs ≥0.3 (*convergent*) and low correlations <0.30 with different constructs (*discriminant*) [50–52]	"1": evidence of convergent validity "1": evidence of discriminant validity
		Known groups comparisons	Significant difference in scores between known groups [50]	"1": the sale differentiates between known groups
		Factor analysis	Factor analysis confirms hypothesized structure [50]	"1": factor analysis confirms hypothesized factor structure
Responsiveness to change				
	Sensitivity to change over time	No widely accepted method of measuring responsiveness to change exists (e.g., ANOVA comparing scores over period where change is hypothesized to have occurred; correlation with people's perceptions of change) [53]	Significant differences in scores over a period of time when the change in sexual functioning is hypothesized to have occurred (e.g., due to treatment); significant correlation between scale scores' and respondent's or other professionals' perceptions of change [53]	"1": evidence of sensitivity to change over time
		Guyatt Responsiveness Statistic: the ability of the scale to capture clinically meaningful change	≥0.2: acceptable responsivity >1.00: high responsivity [54]	

Table 2 Study inclusion and exclusion criteria

Criterion	Included	Excluded
Type of study	Original study	Review paper
	Quantitative	Qualitative
Type of scales	Self-report	Other
Population studied	Women diagnosed with breast cancer	Other populations, including women at risk of developing breast cancer and women diagnosed with Ductal Carcinoma in Situ
Study reporting on the experiences of…	Women diagnosed with breast cancer	Partners, care providers and professionals

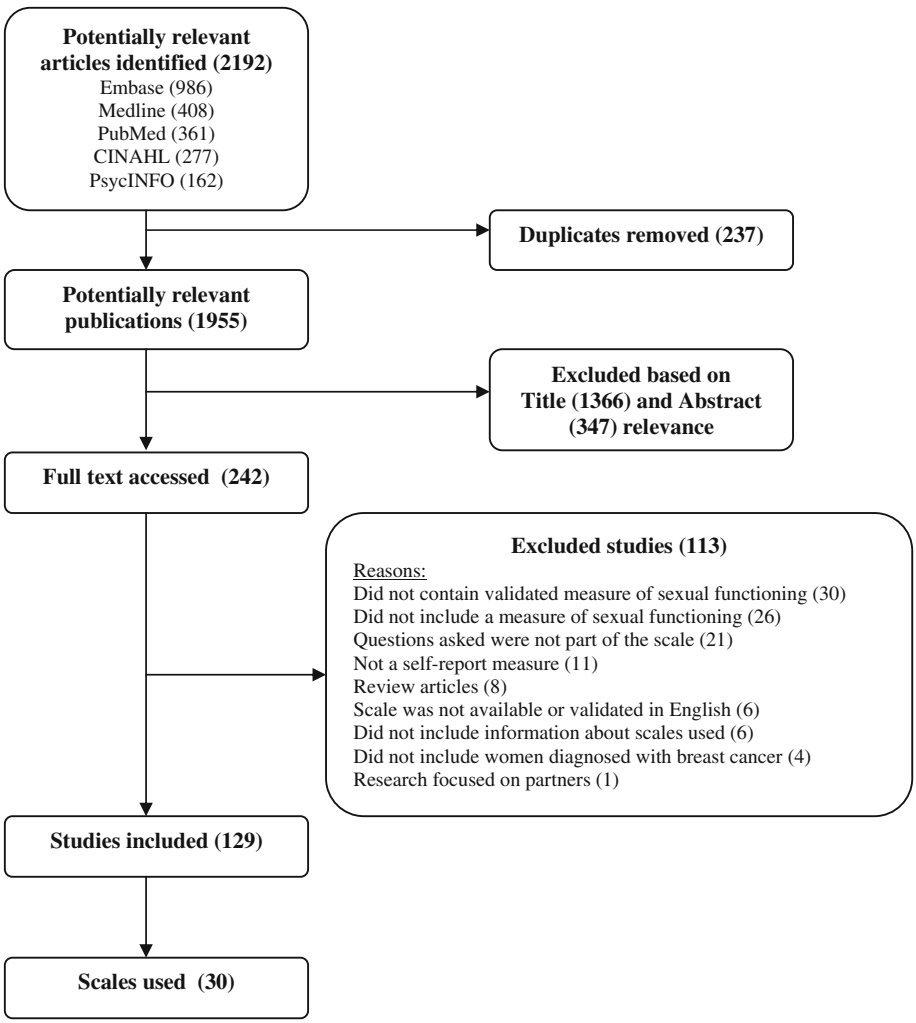

Fig. 1 Flowchart of the systematic review

same scale existed, the results were differentiated by assigning a number in their subscript (e.g., n_1, n_2, denotes sample sizes in two different studies).

Validation sample characteristics

Only four scales (13 %) met the criteria of having adequate sample size and containing women diagnosed with breast cancer (BCPT-SCL [25], CARES [26] Sexual Problem Scale [27], WHOQOL-100 [28]).

Reliability

Seven scales (23 %) met the reliability criteria, that is, having both adequate internal consistency and temporal stability: ASEX [29], FSFI [30], Sexual Self-Schema Scale

[31], and the sexual functioning subscales of the CARES [26], MRS [32], QLACS [33], and WHOQOL-100 [28].

Validity

No scales were awarded full scores (6) for their validity studies, but those with the greatest validity evidence (≥4) included: CSDS [58], FSFI [30], Heatherington Intimate Relationship Scale [34], Sexual Self-Schema Scale [31], SQoL-F [67], MRS [32], and WHOQOL-100 [28].

Responsiveness to change

Only five (17 %) scales included evidence of responsiveness to change (ASEX [29], BIRS [36] (GRISS) [37] BCPT-SCL [25], MENQOL [35]). ASEX and BIRS were able to detect improvements in sexual functioning due to treatment (positive change), BCPT-SCL deterioration of functioning due to breast cancer treatment (negative change), and MENQOL and GRISS clinically meaningful change, regardless of direction.

Acceptability to participants

Only four (13 %) of the scales included information on the degree to which the scale questions are acceptable to the participants (GRISS [37], SAQ [38], CARES [26], QLACS [33]).

DSM-IV-TR/ICD-10 aspects

No scales assessed all five aspects of DSM-IV-TR/ICD-10 female sexual dysfunction. FSFI [30], MFSQ [39], SHF [40], Sexual Problem Scale [27] assessed four aspects, while ASEX [29], MOS-SF [41], SAQ [38], Watt's Sexual Functioning Scale [42], WSBQ-F [43] assessed three.

Overall scores

The overall scores ranged from 2 to 11. The three scales with the highest scores included: FSFI [30] (11), Sexual Problem Scale [27] (10.5), and ASEX [29] (10).

Discussion

Our review has indicated that no one scale obtained full score, indicating superior psychometric properties and coverage of all DSM-5/ICD-10 areas of sexual dysfunction (desire, arousal, orgasm, pain, distress), which is consistent with previous reviews in oncology [10, 17] and general populations [44, 45]. Three highest scoring scales included ASEX, FSFI and Sexual Problems Scale. While FSFI has previously been identified as a good quality scale [10, 18], our review also identified two other scales of similar quality (ASEX, Sexual Problems Scale). In the absence of a "gold standard" sexual dysfunction measure, we recommend that any of these three scales are suitable for use in the breast cancer context, with specific caveats outlined below.

When selecting a measure of sexual dysfunction to use in clinical practice or research, there are three considerations: (1) psychometric properties, to ensure that the variability in scores observed is reflective of the variability in the underlying construct, rather than measurement error [24]; (2) how well the scale measures the construct of interest (DSM-5/ICD-10 aspects of sexual dysfunction); and (3) practical issues (administration, scoring, interpretation).

Only the Sexual Problems Scale has been validated on an adequate-sized breast cancer sample, where it demonstrated good internal consistency and evidence of validity. However, no test–retest data are available, making it less useful for repeated measures. ASEX has been validated on general and psychiatric populations. The FSFI has been validated on community, sexual dysfunction, and gynecologic cancer samples. Hence, for one-off measurement of sexual dysfunction we recommend the Sexual Problems Scale, and for repeated measures the ASEX or FSFI may be more useful.

DSM-5/ICD-10 criteria incorporate when women experience distress due to painful sexual encounters, or disruption in desire, arousal or orgasm. None of the three preferred scales include items measuring distress, and ASEX also does not include items measuring pain; hence, FSFI and the Sexual Problems Scale are recommended as they have the greatest coverage of the DSM-5/ICD-10 dimensions of sexual dysfunction. Additional information about the levels of distress may need to be collected to supplement these scales.

All three scales are relatively brief (ASEX-5, FSFI-19, and Sexual Problems Scale-9 items, respectively) and readily accessible. As yet, these scales do not have electronic versions for ease of administration and scoring. To obtain a total score, ASEX and the Sexual Problems Scale have individual items summed, whereas FSFI's scoring algorithm is more complex with six subscales being summed to yield a total score. All scales can be interpreted to identify potential areas of sexual dysfunction, and the Sexual Problems Scale also takes into account partner variables (i.e., lack of interest in sex). Additionally, FSFI can only be validly interpreted for individuals experiencing sexual activity in the past month. Therefore, the Sexual Problems Scale is considered most practical, as it is relatively short to administer and score, and it can identify when dysfunction is due to partner difficulties.

This review also highlighted ways in which existing measures can be improved. To make these scales more

Table 3 Evaluation of scales that were designed to assess primarily sexual functioning

Scale	Validation sample	Reliability	Content validity	Criterion validity	Construct validity				Responsiveness to change	Acceptability	DSM-5/ICD-10	Total score
					C	D	KG	FA				
Arizona Sexual Experience Scale (ASEX) [30]	$n_1 = 134$ O [29] $n_2 = 247$ O [55]	$C\alpha_1 = 0.9$ [29] $C\alpha_2 = 0.91$ [55] TRR $r_1 > 0.80$ (1–2 weeks) [29]	LR, EF	✔ [29]	×	×	× [29]	✔ [55]	Improvement in scores after 12 week intervention [56]	×	Desire Arousal Orgasm	
Score	0.5	2	1	0.5	2				1	0	3	10
Body Image and Relationships Scale (BIRS) [36]	$n = 96$ BC	$C\alpha = 0.94$ TRR $r = 0.41$–0.80 (2 weeks)	PF	×	✔	×	×	×	Sensitive to treatment effects [57]	×	Nil	
Score	1	1	1	0	1				1	0	0	5
Cues for Sexual Desire Scale (CSDS) [58]	$n = 874$ O	$C\alpha > 0.78$	PF, TH	×	×	✔	✔	✔	×	×	Nil	
Score	1	1	1	0	3				0	0	0	6
Derogatis Sexual Functioning Inventory (DSFI) [59]	$n = 325$, 380 O	$C\alpha = 0.56$–0.94 TRR $r = 0.42$–0.93 (2 weeks)	LR, CE	×	×	×	✔	I	×	×	Desire Orgasm	
Score	1	0	1	0	1				0	0	2	6
Female Sexual Functioning Index (FSFI) [30]	$n_1 = 259$ O [30] $n_2 = 186$ O [60] $n_3 = 568$ O [61] $n_4 = 217$ CA [62]	$C\alpha_1 = 0.89$–0.97 [30] $C\alpha_2 = 0.58$–0.95 [60] $C\alpha_3 = 0.84$–0.98 [61] $C\alpha_4 = 0.85$–0.94 [62] TRR $r_1 = 0.79$–0.88 (2–4 weeks) [30]	LR	×	✔ [30, 60, 62]	×	✔ [30, 60, 62]	✔ [30, 61, 62]	×	×	Desire Arousal Orgasm Pain	
Score	1	2	1	0	3				0	0	4	11
The Golombok Rust Inventory of Sexual Satisfaction (GRISS) [37]	62 couples—O	$C\alpha = 0.61$–0.83 TRR $r = 0.47$–0.84	LR, EF	✔	×	×	✔	×	Moderate correlations between therapists' and patients' ratings of change	×	Orgasm Pain	
Score	0	0	1	1	1				1	0	2	6
Heatherington Intimate Relationship Scale [34]	n_1: 192, 165 O [34] n_2: 194 couples O [63]	$C\alpha > 0.85$ [34, 63]	LR, TH	×	✔ [34]	×	✔ [34]	✔ [63]	×	×	Desire	
Score	0	1	1	0	3				0	0	1	6

Table 3 continued

Scale	Validation sample	Reliability	Content validity	Criterion validity	Construct validity				Responsiveness to change	Acceptability	DSM-5/ICD-10	Total score
					C	D	KG	FA				
The McCoy Female Sexuality Questionnaire (MFSQ) [39]	$n = 318$ O	Cα = 0.76–0.80	EF	×	No studies conducted on the whole 19 item scale, the studies cited were based on subsets of items				×	×	Desire Arousal Orgasm Pain	
Score	1	1	1	0	0				0	0	4	7
Medical outcomes Study Sexual Functioning Scale (MOS-SF) [41]	$n = 1{,}234$ O	Cα = 0.92	LR	×	×	×	✔	×	×	×	Desire Arousal Orgasm	
Score	1	1	1	0	1				0	0	3	7
Relationship and Sexuality Scale [64]	$n = 293$ BC	Cα > 0.77 (not reported for one factor)	×	×	×	×	✔	×	×	×	Desire Orgasm	
Score	1.5	1	0	0	1				0	0	2	5.5
Sexual Activity Questionnaire (SAQ) [38]	$n = 447$, 81 O	TRR $r = 0.65$–1.00 (2 weeks)	LR	×	✔	×	×	×	×	Acceptable rate of item completion	Desire Arousal Pain	
Score	1	0.5	1	0	1				0	1	3	7.5
Sexual Dissatisfaction Scale [65]	$n = 113$, 37 O	Cα = 0.63–0.82	×	×	✔	×	×	×	×	×	Interest	
Score	0	0	0	0	1				0	0	1	2
Sexual History Form (SHF) [40]	$n = 27$–45 [66]	ITC $r = 0.18$–0.85 [66] TRR $r = 0.92$ (2 weeks) [66]	LR, TH, CE	×	✔	×	✔	×	×	×	Desire Arousal Orgasm Pain	
Score	0	1.5	1	0	2				0	0	4	8.5
Sexual Problem Scale [27]	179 DCIS, 345 BC 509 O	Cα = 0.74–0.87	LR	✔	✔	×	×	✔	×	×	Desire Arousal Orgasm Pain	
Score	2	1	1	0.5	2				0	0	4	10.5
Sexual Self-Schema Scale [31]	387 O	Cα = 0.82 TRR $r = 0.98$ (2 weeks)	EF, CE	✔	✔	✔	✔	×	×	×	Nil	
Score	1	2	1	0.5	3				0	0	0	7.5

Table 3 continued

Scale	Validation sample	Reliability	Content validity	Criterion validity	Construct validity				Responsiveness to change	Acceptability	DSM-5/ICD-10	Total score
					C	D	KG	FA				
Sexual Quality of Life Female (SQoL-F) Questionnaire [67]	$n = 730$, 60, 65, 25 O	$C\alpha_1 = 0.95$ $TRR_3 = 0.85$	LR, EF, PF	✔	✔	×	✔	✔	×	30 % did not answer sexuality questions	Distress	
Score	1	1	1	1	3				0	0	1	9
Watts Sexual Functioning Scale [42]	$n = 52$, 17 O	$C\alpha = 0.55$–0.65 TRR $r = 0.83$ (72 h)	EF	×	×	×	✔	×	×	×	Desire Arousal Orgasm	
Score	0	1	1	0	1				0	0	3	6
Wilmoth Sexual Behaviors Questionnaire-Female (WSBQ-F) [43]	$n = 145$ O, 165 BC	$C\alpha = 0.94$ (total scale), $C\alpha = 0.52$–0.94 (subscales) TRR $r = 0.73$–0.88 (period unknown)	LR, PF	×	×	×	✔	✔	×	×	Desire Arousal Orgasm	
Score	1	1.5	1	0	2				0	0	3	8.5

Validation sample: *BC* breast cancer, *CA* cancer, *O* other; Reliability: *Cα* Cronbach's Alpha, *TRR* test–retest reliability, *ITC* item–total correlations; Content validity: *TH* theory, *LR* literature review, *EF* expert's feedback, *PF* participants' feedback, *CE* clinical experience; Construct validity: *C* convergent validity, *D* divergent validity, *KG* known groups, *FA* factor analysis; ✔ evidence cited in paper, × no evidence cited, *I* inconsistent evidence cited (with hypotheses or research)

Table 4 Evaluation of scales that were part of the QOL measures

Scale	Validation sample	Reliability	Content validity	Criterion validity	Construct validity				Responsiveness to change	Acceptability	DSM-5/ICD-10	Total score
					C	D	KG	FA				
Breast Cancer Prevention Trial Eight Symptom Scale (BESS) *Vaginal Problems Subscale* [68]	$n = 11{,}064$ O	×	LR	×	I	×	×	✔	×	×	Pain Arousal	
Score	1	0	1	0	1				0	0	2	5
Breast Cancer Prevention Trial Symptom Checklist (BCPT-SCL) *Vaginal Problems* [25]	$n_1 = 278/196$ BC [25] $n_2 = 208$–863 BC [69]	$C\alpha_1 = 0.618$–0.772 [25] $C\alpha_2 = 0.79$ [69]	LR	×	I [25, 69]	×	✔ [69]	✔ [25, 69]	Score changed with treatment	×	Pain Arousal	
Score	2	0.5	1	0	2.5				1	0	2	9
Cancer Rehabilitation Evaluation System (CARES) *Sexual Subscale* [26]	$n_1 = 479/1047$ CA [26] $n_2 = 779$ CA/ 109 BC [70]	$C\alpha_1 = 0.82$–0.88 (total scale), 0.80–0.88 (subscales) [26] TRR $r_1 = 0.86$ (1 week) [26]	TH	×	I [26]	×	✔ [70]	✔ [26]	No significant change in scores in breast cancer patients [70]	Positive feedback from 86 participants [26]	Desire	
Score	2	2	1	0	2				0	1	1	9
European Organization for Research and Treatment of Breast Cancer (EORTC-BR 23) *Sexual Functioning Subscale* [71]	$n = 170$ (Dutch), 168 (Spanish), 158 (American) BC	$C\alpha = 0.87$–0.94	EF, LR, PF, CE	×	✔	×	✔	×	×	11–14 % of participants found one or more of sexuality items too personal to answer	Desire	
Score	1	1	1	0	2				0	0	1	6
European Organization for Research and Treatment of Breast Cancer (EORTC) Patient Reported Outcomes (PRO) *Sexual Functioning Scale* [72]	BC	×	LR, EF, PF	×	Not cited but psychometric validation of the scale is currently underway				×	×	×	
Score	1	0	1	0	0				0	0	0	2
Long-Term Quality of Life Breast Cancer (LTQOL-BC) *Sexual Function Subscale* [73]	$n = 285$ BC	$C\alpha = 0.68$	PF	×	✔	×	×	✔	×	×	Desire Distress	
Score	1.5	0	1	0	2				0	0	2	6.5

Table 4 continued

Scale	Validation sample	Reliability	Content validity	Criterion validity	Construct validity				Responsiveness to change	Acceptability	DSM-5/ICD-10	Total score
					C	D	KG	FA				
Menopause specific quality of life questionnaire (MENQOL) *Sexual Domain* [35]	$n_1 = 107$ O [35] $n_2 = 108$ BC [74] $n_3 = 148$ O [75]	C$\alpha_1 = 0.68$ [35] C$\alpha_2 = 0.673$ [75] TRR $r_2 = 0.451$–0.688 (5–9 weeks) [75]	EF, LR, CE, PF	✔	✔ [75]	×	×	✔ [74]	Guyatt statistic 0.24	×	Desire Arousal	
Score	1	0.5	1	0.5	2				1	0	2	8.0
Menopause Rating Scale (MRS) *Urogenital Factor* [32]	$n > 1{,}000$ O	C$\alpha = 0.7$ TRR $r = 0.82$ (2 weeks)	EF, CE	✔	✔	×	×	✔	×	×	Desire Arousal	
Score	1	2	1	1	2				0	0	2	9
Psychosocial Adjustment to Illness Scale-Self Report (PAIS-SR) *Sexual Relationship Domain* [76]	$n_1 = 331$ CA/BC [77] $n_2 = 280$ O; 41 BC [78]	C$\alpha_1 = 0.92$ [77] C$\alpha_2 = 0.86$ [78]	×	×	✔ [77, 78]	×	×	✔ [77, 78]	×	×	Desire	
Score:	1.5	1	0	0	2				0	0	1	5.5
Quality of Life in Adult Cancer Survivors (QLACS) *Sexual Problems Scale* [33]	$n = 94$ BC	C$\alpha = 0.72$–0.95 (data not shown) TRR $r = 0.89$	×	×	Not cited for sexual problems scale				Sexual problem scale was not responsive to change	3.2 % missing data	Desire Distress	
Score	1	2	0	0	0				0	1	2	6
Women's Health Questionnaire (WHQ) *Sexual Behaviors Factor* [79]	$n_1 = 682$ O [79], $n_2 = 737$ O [80], $n_3 = 850$ O [81]	C$\alpha_1 = 0.68$ [79] TRR $r_2 > 0.78$ (2 weeks) [80] $r_3 > 0.69$ (1 week) [81]	LR	×	×	×	✔ [81]	✔ [79–81]	×	×	Desire	
Score	1	1	1	0	2				0	0	1	6
World Health Organization Quality of Life Assessment Instrument (WHOQOL-100) *Sexual Activity Scale* [28]	$n_1 = 356$ BC [3] $n_2 = 300$ from each of 15 countries, O [28] $n_3 = 144$ O [82]	C$\alpha > 0.80$ TRR $r_1 = 0.77$ (6 months) [3] $r_3 = 0.86$ (2–4 weeks) [82]	LR, PF	✔	I [3]	✔ [3]	×	✔ [3]	×	×	Distress	
Score	2	2	1	1	2				0	0	1	9

Validation sample: *BC* breast cancer, *CA* cancer, *O* other; Reliability: *C*α Cronbach's Alpha, *TRR* test–retest reliability; Content validity: *TH* theory, *LR* literature review, *EF* expert's feedback, *PF* participants' feedback, *CE* clinical experience; Construct validity: *C* convergent validity, *D* divergent validity, *KG* known groups, *FA* factor analysis; ✔ evidence cited in paper, × no evidence cited, *I* inconsistent evidence cited (with hypotheses or research)

psychometrically meaningful for breast cancer population, they would benefit from replication of validation studies in this context. Future research should focus on demonstrating concurrent validity, as many validation studies did not report these data. Demonstrating concurrent validity is more difficult when there is no acceptable "gold standard," but researchers are encouraged to use the three scales identified above for this purpose. Generally, all scales can be further improved by additional items to ensure adequate coverage of all dimensions aspects of sexual dysfunction [15, 16], in particular distress. Although the evaluation of the cultural suitability and sensitivity of scales was beyond the scope of this review, some scales have validation data for different languages and cultures (e.g., FSFI, MFSQ, SAQ, EORTC-BR-23, WHOQOL-100). Future studies should continue to investigate cross-cultural properties of these sexual dysfunction scales.

In conclusion, this comprehensive systematic review builds upon and extends prior work concerning sexual dysfunction in oncology [10, 17, 18], by focusing specifically on the breast cancer context. Strengths of the research are that it was based on a rigorous psychometric evaluation of measures and an assessment of the extent to which existing measures meet the diagnostic criteria for sexual dysfunction [15, 16]. The scoring system provided a systematic way to summarize the extent to which the scales met the psychometric and DSM-V/ICD-10 criteria. The limitation of the review is that it focused only on studies published in the English language, leading to possible bias.

Our conclusions are of equal importance to clinicians and researchers alike, for whom the selection of appropriate measures of sexual dysfunction will facilitate clinical consultation and discussion with patients, or as critical outcomes and endpoints of clinical trials.

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'The Female Sexual Function Index (FSFI): evaluation of acceptability, reliability, and validity in women with breast cancer'

Numerous scales for measuring sexual dysfunction have been used thus far with women with breast cancer. The systematic review in previous chapter aimed to comprehensively evaluate psychometric properties and the coverage of the areas of sexual dysfunction by assigning each scale found in breast cancer literature a score. The scales with highest scores were recommended for clinicians and researchers to use to screen for sexual dysfunction.

Unfortunately, this review was not able to identify a 'gold standard' measure, as no single scale satisfied all the criteria that were used for evaluation. In relation to the psychometric properties, scales generally lacked validation on breast cancer populations. In relation to the coverage of the DSM-5/ICD-10 areas of sexual dysfunction (American Psychiatric Association, 2013; World Health Organization, 2004), many of the scales neglected to measure distress, which is necessary for any diagnosis of sexual dysfunction.

The most promising scale identified (highest scoring) was the Female Sexual Function Index – FSFI (Rosen et al., 2000), which has shown excellent psychometric properties as well as containing questions covering most areas of sexual dysfunction – desire, arousal, orgasm and pain. However, no previous studies have reported on the FSFI's performance when administered to women diagnosed with breast cancer.

The following chapter reports on the findings of the FSFI validation in the breast cancer context. Apart from the psychometric properties that have been systematically investigated, this study investigated the acceptability of the questions to women with breast cancer, another frequently-neglected aspect of scale development and validation that the previous chapter has highlighted.

This study was published in Supportive Care in Cancer:

Bartula, I., & Sherman, K. A. (2015). The Female Sexual Functioning Index (FSFI): evaluation of acceptability, reliability and validity in women with breast cancer *Supportive Care in Cancer*, 23(9), 2633-2641. doi: 10.1007/s00520-015-2623-y

Additionally, material from this study was presented at the Australasian Society for Behavioural Health and Medicine 11th Annual Scientific Meeting in Auckland, 12th February 2014 (please see Appendix III for presentation)

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ORIGINAL ARTICLE

The Female Sexual Functioning Index (FSFI): evaluation of acceptability, reliability, and validity in women with breast cancer

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Abstract
Purpose Sexual dysfunction commonly arises for women following diagnosis and treatment of breast cancer. The aim of this study was to systematically evaluate the acceptability, reliability, and validity of the Female Sexual Functioning Index (FSFI) when used with these women.
Methods Sexually active women previously diagnosed with breast cancer (N=399) completed an online questionnaire including the FSFI and measures of acceptability (ease of use, relevance), sexual functioning, body image, fatigue, impact of cancer, physical and mental health, and relationship adjustment. Reliability and validity were evaluated using standard scale validation techniques.
Results Participants indicated a high degree of acceptability. Excellent internal consistency (α=0.83–0.96) and test–retest reliability (r=0.74–0.86) of the FSFI were evident. According to the confirmatory factor analysis, the best fit was achieved with removal of item 14 (regarding the extent of emotional closeness with the partner) and six subscales (desire, arousal, lubrication, orgasm, satisfaction, pain), without a total score (TLI=0.96, CFI=0.97, RMSEA=0.07). Correlations with measures of sexual functioning and related constructs provided evidence for convergent and divergent validities, respectively. All but one subscale (orgasm) discriminated between women who are, and are not, currently receiving treatment for breast cancer (discriminant validity).
Conclusions These findings indicate that not only is the FSFI psychometrically sound when used with women with breast cancer, but it is perceived as being easy to use and relevant. It is recommended that the FSFI subscale scores can be used in both clinical and research settings as a screening tool to identify women experiencing sexual dysfunction following breast cancer.

Keywords Breast neoplasms · Sexual dysfunctions (psychological) · Sexual dysfunctions (physiological) · Psychosexual dysfunctions · Questionnaires · DSM-V

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Introduction

Breast cancer is the most frequently diagnosed female cancer [1]. Improvements in early detection screening and treatment approaches have contributed to high survival rates [1], leading to an increased focus on quality of life issues, including sexual functioning [2]. Breast cancer and its treatment uniquely impact on a woman's sexuality in that partial or complete removal of the breast may lead to changes in feminine and sexual identity [3]. Surgery may also result in reduced arousal from sexual stimulation [4], and hormone therapies often induce menopause and reduce sexual responsiveness [5]. Despite women with breast cancer reporting high prevalence of sexual functioning problems [6], they are not routinely addressed in clinical consultations [7], as neither patients nor practitioners are comfortable initiating discussion of this topic [7, 8]. A quick, self-report sexual functioning screening tool would, therefore, be useful in identifying women who experience sexual functioning difficulties and may facilitate clinical conversations.

There is a paucity of self-report measures that are accepted and validated in the breast cancer population [9]. In a recent systematic review [9], the Female Sexual Functioning Index

(FSFI) [10] was identified as a promising measure because it incorporates criteria of sexual dysfunction, as defined by internationally recognized diagnostic systems [11, 12], and has demonstrated psychometric properties in nonbreast cancer populations. The FSFI has had psychometric validation studies conducted on healthy women [10], and women diagnosed with sexual dysfunction disorders [10, 13, 14], gynecological cancer [15], vulvar intraepithelial neoplasia [16], vulvodonia [17], and chronic pelvic pain [18]. These studies have shown excellent internal consistency [10, 13–18], test–retest reliability [10, 18], and discriminant validity [10, 13–18]. There is also evidence of divergent validity, through moderate correlations with measures of marital adjustment [10, 13], depression, physical and emotional well-being [15], and low-to-moderate correlations with quality of life [16]. Studies conducting exploratory and confirmatory factor analyses provide support for calculating five [10, 14, 15] and six [19] subscales, respectively. Although the FSFI is widely used in breast cancer research [9], no empirical studies have systematically investigated the psychometric properties of this measure in this context.

An important property of any scale is the level of acceptability to the target users [9], concerning the ease with which respondents answer items and their comfort in answering items of a sensitive nature (e.g., relating to sexual experiences). This often-neglected characteristic of scales is a key component of the overall usefulness of any measure and an indicator of its likely uptake in clinical use. However, no prior validation studies of the FSFI in any context [10, 13–19] have assessed the user acceptability of this measure.

The overall aim of this study was to assess the appropriateness of the FSFI when administered to breast cancer patients. We extended prior knowledge about the adequacy of the FSFI by examining the following: (1) the extent to which the FSFI items were regarded as being acceptable/applicable to a breast cancer population, and (2) convergent validity, both not previously addressed in any of the FSFI validation studies [10, 13–19]. Additionally, we examined the factor structure of the FSFI using confirmatory factor analysis (CFA), an approach which has not previously been undertaken with oncological populations [15].

Materials and methods

Study design and participants

Following approval to conduct this research from the Macquarie University Human Research Ethics Committee, the Breast Cancer Network of Australia (BCNA), a nationwide consumer support organization, sent the study invitation via e-mail to all members registered as being interested in research participation. The invitation contained the direct link to the online study questionnaire. Women who (1) had a diagnosis of breast cancer or ductal carcinoma in situ (DCIS), and (2) were over 18 years of age were invited to participate.

Upon completion of the time 1 questionnaire (containing demographic information, the FSFI, and other measures used for validity), participants were invited to provide their e-mail address to participate in the second part of the study (time 2). Two weeks after the time 1 survey completion, interested participants were sent a link to complete the time 2 survey (consisting of the FSFI and acceptability items). Each survey took approximately 20–30 min to complete.

Of the 597 women who responded to the invitation, 23 (4 %) did not provide consent, and 54 (9 %) did not complete the survey, leaving 520 (87 %) women who completed the survey. Completers had more years of education ($\chi^2=14.13$, $d.f.=6$, $p<0.05$), were older ($\chi^2=11.97$, $d.f.=5$, $p=0.05$), and had worse body image ($t=-1.95$, $d.f.=544$, $p=0.05$) than noncompleters. Of those completing the time 1 survey, 366 (70 %) women indicated willingness to undertake the time 2 survey; 255 (70 %) of this subsample responded to the time 2 survey invitation, but one (0.3 %) did not consent, and 15 (4 %) did not complete the survey, leaving 249 (68 % of the subsample) participants who completed the time 2 survey.

Measures

The FSFI [10] is a 19-item (5-point Likert-type) scale measuring female sexual dysfunction. The English version of the FSFI was used, as originally published [10]. Individual items are designed to be summed into six subscales (desire, arousal, lubrication, orgasm, satisfaction, and pain), which can then be combined to produce a total score (range 2–36), with higher scores indicating better sexual functioning. The FSFI contains 15 items with a zero-scored option indicating no recent sexual activity. Although the FSFI scoring algorithm assumes that zero-scored responses to these items represent the lowest level of sexual functioning [10], this interpretation may bias the results of such individuals toward greater dysfunction [15]. Therefore, for this reason, only participants who reported recent sexual activity were included in the FSFI acceptability, reliability and validity studies. Descriptive comparisons were made between sexually active and inactive women.

User acceptability of the FSFI was assessed with four 5-point Likert-type scale items (1="strongly disagree" to 5="strongly agree") developed by the researchers: "I felt comfortable answering the questions," "The questions were easy to complete," "The questions were relevant to my experiences," and "The questionnaire was about the right length." Mean scores were calculated with higher scores indicating greater user acceptability. A final item was open ended: "Please provide any feedback about the questionnaire above."

Several other measures, summarized in Table 1, were administered together with the FSFI in order to establish evidence of convergent and divergent validities; all scales for this

Table 1 Measures used

Construct	Reason for administration	Scale	Scale structure	Score range and interpretation
Sexual functioning	Convergent validity	Cancer Rehabilitation Evaluation System (CARES); Sexual Functioning Subscale [20]	8 items; 5-point, Likert-type	Total score 0–40 Higher score—more severe sexual dysfunction
		World Health Organization Quality of Life Assessment Instrument (WHOQOL-100) Sexual Activity Scale [21]	4 items; 5-point, Likert-type	Total score 4–20 Higher score—better sexual functioning
Body Image	Divergent validity	Body Image Scale (BIS) [22]	10 items; 4-point Likert-type	Total score 0–30 Higher score—more severe body image
Fatigue		Fatigue Assessment Scale (FAS) [23]	10 items; 5-point Likert-type	Total Score 10–50 Higher score - greater fatigue
Impact of breast cancer diagnosis		Impact of Event Scale (IES) [24]	15 items; 4-point Likert-type	Total score 0–75 Higher score—greater negative impact
Physical and mental health		Depression, Anxiety and Stress Scales (DASS-21) [25]	Depression, Anxiety and Stress Subscales; 21 items; 4-point Likert-type	Subscale scores 7–28 Higher score—more severe symptoms
		Medical Outcomes Studies Health Survey (SF-20) [26]	Physical and Mental Health Subscales; 20 items; 3-, 5-, 6-point Likert-type	Subscale scores 0–1400 (physical health), 0–600 (mental health) Higher score—better functioning
Relationship adjustment		Revised Dyadic Adjustment Scale (RDAS) [27]	14 items; 5-, 6-point Likert-type	Total score 0–69 Higher score—better adjustment

purpose have acceptable psychometric properties in oncology [2, 20, 28–30], health-related [26], and general [27, 31] populations.

Statistical analyses

Missing values

For all scales, mean scores were calculated for participants with at least 80 % of data available for a particular measure, a preferred method of missing data estimation when scale internal consistencies exceed 0.70 [α ranged from 0.71 (DASS-Depression) to 0.94 (BIS)], and there is less than 30 % data missing [32]. For participants with more than 20 % data missing, the conservative pair-wise deletion method was used [32]. For the CFA, the recommended full information maximum likelihood method was used to estimate missing values [33].

Internal consistency was indicated by Cronbach's α over 0.70 [34]. Test–retest reliability was assessed by correlating FSFI scores at times 1 and 2, with acceptable values over 0.70 [34, 35].

Construct validity was demonstrated in two ways: (1) convergent validity, examined by Pearson's correlations between the FSFI and other scales of sexual functioning, expecting moderate to high ($r \geq 0.3$) correlations [35], and (2) divergent validity, examined by Pearson's correlations with related, but different, constructs: body image, fatigue, impact of cancer, physical and mental health, and relationship adjustment (see Table 1), expecting low to moderate correlations ($r \leq 0.5$) [35]. Discriminant validity was demonstrated by examining t test differences in women currently receiving, and not currently receiving, cancer treatment.

CFA examined the FSFI subscale structure using maximum likelihood model estimation, an appropriate method when Likert-type items have more than three response categories and are not significantly (>1) differentially skewed [36]; the FSFI has five response categories, and preliminary analyses revealed that all items had acceptable skewness (range 0.03–0.98). Multiple models were tested [33], based on theoretical conceptualizations of the FSFI [10] (6 subscales: desire, arousal, orgasm, lubrication, pain, and satisfaction), and current conceptualization of sexual dysfunction [11], as well as prior exploratory factor analytic studies of the FSFI with women from the general population and those diagnosed with sexual dysfunctions and gynecological cancer [10, 14, 15], which provided support for five subscales (desire/arousal, orgasm, lubrication, pain, and satisfaction). Models containing (1) only subscales and (2) subscales and a total were tested [37]. Model fit was assessed using the Tucker–Lewis index (TLI), comparative fit index (CFI), and root mean square error of approximation (RMSEA) [38]. For acceptable fit, the TLI and CFI values should be over 0.95, while RMSEA should be less than 0.08 [38]. The Akaike

Table 2 Demographic information

	Included women (n=399)		Excluded women (n=121)	
	No.	%	No.	%
Country of birth:				
Australia	315	78.9	96	79.3
Other countries	84	21.1	25	20.7
Relationship status[a]:				
Partnered	362	90.7	65	53.7
Single	37	9.3	56	46.3
Children:				
Yes	343	86	88	72.7
No	0	0	0	0
Missing	56	14	33	27.3
Age:				
Mean	55.88		53.90	
SD	9.60		8.76	
Education:				
High school or less	109	27.3	27	22.3
College or some university	137	34.3	45	37.2
Bachelor's degree	88	22.1	23	19.0
Postgraduate studies	64	16	26	21.5
Missing	1	0.3	0	0
Employment:				
Employed	254	63.7	72	59.5
Unemployed	26	6.5	8	6.6
Retired	115	28.8	39	32.2
Missing	4	1.0	2	1.7
Diagnosis[b]:				
DCIS	73	18.3	27	22.3
Early stage breast cancer	273	68.4	71	58.7
Metastatic breast cancer	27	6.8	16	13.2
Missing	26	6.5	7	5.8
Time since diagnosis[b]:				
Mean (years)	3.66		4.56	
SD	3.90		4.41	
Surgery type:				
Lumpectomy / wide local excision	188	47.1	44	36.4
Single mastectomy	115	28.8	45	37.2
Double mastectomy	29	7.3	13	10.7
Mastectomy with reconstruction	67	16.8	19	15.7
Adjuvant therapies:				
Ever received:				
No treatment	25	6.3	10	8.3
Hormone, radiation OR chemotherapy only	101	25.3	26	21.5
Two or more therapies	273	68.4	85	70.2
Currently receiving:				
No treatment	163	40.9	43	35.5
Hormone, radiation OR chemotherapy	223	55.9	71	58.7
Two or more therapies	6	1.5	4	3.3
Missing	7	1.8	3	2.5
Menopausal status				
Prior to cancer:				
Premenopausal	246	61.7	70	57.9
Postmenopausal	149	37.3	51	42.1
Missing	4	1	0	0
Current:				
Premenopausal	69	17.3	15	12.4
Postmenopausal	323	81	103	85.1
Missing	7	1.8	3	2.5

[a] $p<0.01$, [b] $p<0.05$

information criterion (AIC) was used to compare fit among models, with smaller values indicating better fit [39].

The threshold for statistical significance was set to $p<0.05$. The CFA was conducted using AMOS (Version 21, Armonk, NY: IBM Corp). All other analyses were conducted using SPSS (Version 21, Armonk, NY: IBM Corp).

Results

Sample characteristics

Time 1 sample demographic and medical characteristics are provided in Table 2. In total, 180 responses (time 1, 121, 23 %; time 2, 59, 25 %) were excluded due to participants reporting no sexual activity during 4 weeks prior to study participation, leaving a final analyzable sample of n=399 (time 1), n=180 (time 2). Sexually inactive women were more likely to be single (χ^2=86.58, $d.f$=1, $p<0.01$), diagnosed with metastatic breast cancer (χ^2=6.76, $d.f.$ = 2, $p<0.05$), and had greater time since diagnosis (t=2.15, $d.f$=517, $p<0.05$). They experienced more fatigue (t=2.49, $d.f.$ = 174, $p<0.01$), anxiety (t=2.06, $d.f.$ = 167, p=0.02), depression (t=2.57, $d.f.$ = 174, $p<0.01$), and body image problems (t=2.95, $d.f.$ = 518, $p<0.01$), as well as lower relationship adjustment (t=−2.86, $d.f.$ = 423, $p<0.01$) and overall sexual satisfaction (t=−8.13, $d.f.$ = 201, $p<0.01$).

Acceptability to patients

A total of 180 women completed acceptability questions. The FSFI was rated positively as the women felt comfortable answering questions (M=4.15, SD=0.82), found questions easy

to complete (M=4.16, SD=0.78), and relevant to their experiences (M=3.96, SD=0.99), and that the FSFI was the right length (M=4.23, SD=0.67). Eighty-six (48 %) women provided open-ended feedback about user acceptability suggesting improvements to the FSFI by including items to assess the following: (1) reasons for sexual dysfunction, (2) the contribution of the partner's sexual difficulties, (3) the use of artificial lubricants, and (4) precancer sexual functioning.

Reliability

Reliability coefficients are presented in Table 3. The average time between time 1 and time 2 was 21 days (SD=6.11). All reliability coefficients were acceptable [from 0.89 (satisfaction) to 0.96 (lubrication)] and consistent across time. Test–retest reliability coefficients ranged from 0.75 (pain) to 0.86 (desire). Internal consistency and test–retest reliability of the satisfaction subscale improved with the removal of item 14.

Validity

The pattern of correlations (see Table 3) supports convergent and divergent validities for the FSFI. In general, significant moderate to large correlations (r=0.44–0.79, p<0.01) were found between the FSFI and other measures of sexual functioning (convergent validity). Significant low to moderate correlations in expected directions were found between the FSFI and constructs related to sexual dysfunction: body image, fatigue, impact of cancer, physical functioning, depression, anxiety, and relationship adjustment, providing evidence for divergent validity.

Women currently receiving cancer treatment reported significantly lower desire (t=2.10, $d.f.$ = 389, p<0.05), arousal (t=2.77, $d.f.$ = 383, p<0.01), lubrication (t=2.48, $d.f.$ = 375, p<0.05), satisfaction (t=2.05, $d.f.$ = 379, p<0.05), and pain (t=3.93, $d.f.$ = 354, p<0.01) than women not receiving treatment. There was a nonsignificant trend for these women to be differentiated by scores on the orgasm subscale (t=1.91, $d.f.$ = 381, p=0.057).

The CFA results are presented in Table 4. With item 14 removed, model 2 (six subscales, no total score, as shown on Fig. 1 showed an acceptable (TLI=0.96, CFI=0.97, RMSEA=0.07) and superior fit compared with all other models (AIC=493.65). All subscales had acceptable standardized regression weights (range 0.87–0.95; see Table 5), and correlations among subscales were significant, but not uniform (r=0.33–0.88, p<0.01).

Table 3 Internal consistency, test–retest reliability, correlations with other measures of sexual functioning (convergent validity), and related constructs (divergent validity)

	Desire	Arousal	Lubrication	Orgasm	Satisfaction	Pain	Mean (SD)
Internal consistency							
With item 14							
Time 1					0.83		
Time 2					0.86		
Without item 14							
Time 1	0.93	0.94	0.96	0.94	0.89	0.92	
Time 2	0.92	0.93	0.95	0.92	0.89	0.91	
Test–retest reliability (n=159)							
With item 14					0.74		
Without item 14	0.86	0.82	0.78	0.80	0.76	0.75	
Convergent validity							
CARES	−0.66*	−0.70*	−0.54*	−0.63*	−0.63*	−0.48*	28.51 (6.28)
WHOQOL-100	0.54*	0.61*	0.44*	0.55*	0.73*	0.49*	11.77 (4.31)
Divergent validity							
Body image	−0.22*	−0.26*	−0.11	−0.24*	−0.33*	−0.20*	10.25 (8.02)
Fatigue	−0.18*	−0.25*	−0.20*	−0.22*	−0.23*	−0.16*	21.59 (6.83)
Impact of cancer	−0.14*	−0.11		−0.12	−0.15*	−0.13	14.95(15.22)
Physical health	0.12	0.16*	0.15*	0.17*	0.13*	0.11	915.89 (329.82)
Depression	−0.13*	−0.22*	−0.12	−0.19*	−0.19*		10.07 (3.72)
Anxiety	−0.11	−0.16*	−0.12	−0.16*	−0.13*		9.24 (2.73)
Relationship adjustment	0.26*	0.27*	0.12	0.22*	0.42*	0.13	47.36 (7.48)

Only correlations that were significant at 0.05 level were noted

*$p \leq 0.01$

Table 4 CFA results

	TLI	CFI	RMSEA	AIC
MODEL 1: Single total score	0.54/0.53[a]	0.63/0.63[a]	0.22/0.23[a]	3212.62/3121.06[a]
MODEL 2: 6 Subscales	0.95/0.96[a*]	0.96/0.97[a*]	0.08/0.07[a*]	584.23/493.65[a*]
MODEL 3: 5 Subscales	0.89/0.90[a]	0.92/0.92[a]	0.11/0.11[a]	920.60/831.73[a]
MODEL 4: 6 Subscales+total	0.93/0.94[a]	0.95/0.95[a]	0.09/0.08[a]	700.12/611.32[a]
MODEL 5: 5 Subscales+total	0.88/0.88[a]	0.91/0.91[a]	0.11/0.12[a]	1022.19/933.27[a]

TLI Tucker–Lewis index, *CFI* comparative fit index, *RMSEA* root mean square error of approximation, *AIC* Akaike information criterion

[a] If item 14 is omitted

[*] Acceptable model

Discussion

This study investigated the level of user acceptability of the FSFI and whether it is psychometrically sound, when administered to women with breast cancer. Generally, participants found the FSFI to be the right length, easy to complete, and relevant to their experiences. The scale also demonstrated excellent psychometric properties (high internal consistency, test–retest reliability, and evidence of construct validity).

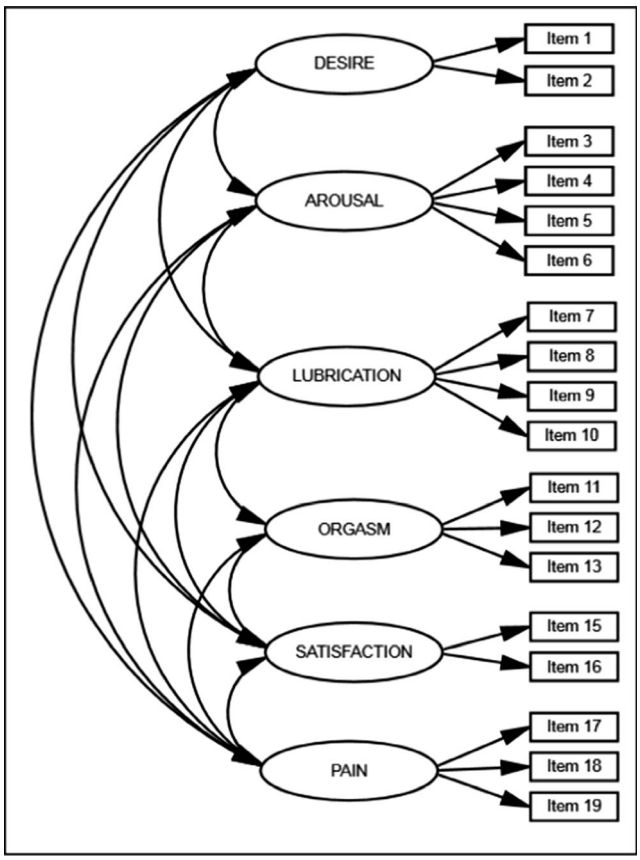

Fig. 1 The acceptable confirmatory analysis model (model 2)

On the basis of these findings, it is recommended that when using the FSFI in clinical practice, six subscales are calculated: desire, arousal, lubrication, orgasm, satisfaction, and pain, consistent with the original theoretical conceptualization of the scale [10]. This is supported by the present study CFA results and previous studies on nonbreast cancer populations [19], but differs from other studies of exploratory factor analysis reporting a five-factor solution, with desire and arousal combined in a single factor [10, 14, 15]. Furthermore, it is recommended that only subscales are calculated, rather than combining them into a total score, as the models containing the total score did not show adequate fit [40]. Clinically, the subscale scores may be more meaningful as they can identify women's difficulties in one or more areas of sexual functioning, as identified by diagnostic systems [11, 12]. Additionally, when administering the FSFI to women diagnosed with breast cancer, practitioners should consider removing item 14 (regarding emotional closeness with one's partner), as the CFA model fit significantly improved when this was excluded from the scale. Item 14 contributed to more than one subscale, as the level of emotional intimacy impacts on aspects of sexual functioning other than satisfaction [41].

The final caveat relates to the use of the FSFI with women not reporting recent sexual activity. As the psychometric validation in the present study was only conducted on sexually active women, the validation results are only applicable to this subset of women. It is, therefore, advised that when using the FSFI with nonsexually active women, results are interpreted with caution, as low scores do not necessarily indicate sexual dysfunction. For these women, it is recommended that the FSFI administration is supplemented with either a clinical interview or another questionnaire exploring reasons for sexual inactivity. During a clinical interview, the interviewer may investigate whether sexual inactivity is due to difficulties in sexual response (desire, arousal, orgasm, and pain) or other factors (absence of partner, partner's difficulties, conflict, fatigue, etc.). The Sexual Activity Questionnaire (SAQ) [42] has

Table 5 Acceptable model (model 2): standardized regression weights, standard errors, and subscale correlations

		Desire	Arousal	Lubrication	Orgasm	Satisfaction	Pain
Standardized regression weights (standard errors)	Item 1	0.93					
	Item 2	0.94 (0.04)					
	Item 3		0.85				
	Item 4		0.92 (0.04)				
	Item 5		0.88 (0.04)				
	Item 6		0.94 (0.05)				
	Item 7			0.92			
	Item 8			0.95 (0.03)			
	Item 9			0.90 (0.04)			
	Item 10			0.94 (0.03)			
	Item 11				0.92		
	Item 12				0.92 (0.03)		
	Item 13				0.89 (0.03)		
	Item 15					0.90	
	Item 16					0.91 (0.05)	
	Item 17						0.87
	Item 18						0.92 (0.04)
	Item 19						0.94 (0.04)
Subscale correlations	Desire	1.00*					
	Arousal	0.70*	1.00*				
	Lubrication	0.48*	0.67*	1.00*			
	Orgasm	0.56*	0.85*	0.64*	1.00*		
	Satisfaction	0.51*	0.62*	0.40*	0.56*	1.00*	
	Pain	0.33*	0.40*	0.59*	0.37*	0.36*	1.00*

a checklist that may be helpful in discerning the reasons for absence of sexual activity and may supplement the information obtained from the FSFI.

Strengths of the present study include sufficient sample size [43] and an examination of the acceptability of questions to participants, and convergent validity, all of which are important, but often neglected, aspects of validating sexual functioning scales [9]. However, the participants self-selected, which may have biased the results. The study was conducted in Australia, and although it is likely that the results are generalizable to English-speaking developed countries, this may need empirical verification. The proportion of women reporting sexual inactivity was higher than previously reported in nonbreast cancer FSFI validation studies [10, 15], likely reflecting the older age at which breast cancer is typically diagnosed and that sexual activity tends to decrease with age [44].

Future research should focus on (1) adapting the FSFI questions to be applicable to women with no recent sexual activity; (2) making the FSFI more meaningful to breast cancer survivors by including additional questions about reasons for sexual dysfunction, the partner's contribution, the role of artificial lubricants and precancer functioning; (3) demonstrating whether the FSFI can detect clinically meaningful change in sexual functioning; and (4) demonstrating factorial invariance across age, menopausal status, and treatment.

In conclusion, this study provides evidence that the FSFI is a suitable tool to screen for sexual dysfunction in women with breast cancer. Difficulties with sexual functioning may occur at any stage of breast cancer diagnosis and treatment [45], and the FSFI can be used throughout this period to monitor these symptoms and identify women who would benefit from more intensive intervention. The FSFI could be useful in both clinical practice and research to measure outcomes of biological and/or psychological interventions implemented to treat sexual dysfunction. As the FSFI does not require additional training to administer, score, and interpret the results, it can be used by a variety of professionals, regardless of their experience in working with sexual difficulties, including medical practitioners, nurses, psychologists, counselors, sex therapists, social workers, occupational therapists, and researchers. General empathy, compassion, and communication skills would be helpful in building rapport and trust, as well as further assessing the levels of distress the women are experiencing due to their sexual difficulties, which is crucial for diagnosis of sexual dysfunction [11, 12].

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Conflict of interest The authors report no conflicts of interest.

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'Development and Initial Validation of the Female Sexual Function Index adaptation for breast cancer patients (FSFI-BC)'

The Female Sexual Function Index (FSFI) has been shown to have excellent psychometric properties for use in breast cancer populations (Chapter 3) and the women themselves found the questions in the FSFI to be generally acceptable and appropriate. The previous chapter reported on the evidence for calculating the subscale scores (desire, arousal, lubrication, orgasm, pain and satisfaction) rather than summing these into a total score. Clinically, the subscale scores may be more useful as they provide information about which aspect(s) of sexual functioning are of the greatest concern for a woman with breast cancer.

With the evidence from the previous chapter, clinicians and researchers can implement the FSFI with confidence, knowing that the scale is reliable, valid and that, in general, the women find it an acceptable scale to complete. However, the long-standing problems of the FSFI have not been addressed – its limited use with women who are not sexually active and the absence of questions measuring distress. If this scale is to be used in routine care, this is concerning as about 25% of women with breast cancer report no recent sexual activity (Chapter 3). Additionally, in its current form, the FSFI can only identify areas of sexual difficulty, rather than dysfunction. In their feedback, the women with breast cancer thought that the FSFI could further be improved by incorporating a measure of sexual functioning prior to cancer, assessing the partner's role in any reported sexual difficulties and the effectiveness of artificial lubricants that many of them were using to counteract some of the treatment side effects.

To overcome these limitations, an adaptation of the FSFI was created – the Female Sexual Function Index – Breast Cancer (FSFI-BC). The FSFI-BC aims to maintain the structure of the original FSFI with the following additions: (1) a separate scale that the women who are not sexually active are asked to complete; (2) questions enquiring about the level of distress women are experiencing due to reported sexual difficulties; (3) questions assessing perceived changes in sexual functioning following breast cancer diagnosis; (4) questions enquiring about the effectiveness of artificial lubricants. Furthermore, the FSFI-BC contains questions enquiring about the role of the partner in reported sexual difficulties. The scores on these questions do not contribute to a subscale, but can be used to aid the interpretation of the FSFI-BC subscale scores.

The Chapter 4 reports on the development and the validation of the FSFI-BC.

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Please note that the FSFI-BC was published as an online resource. The FSFI-BC and scoring instructions can be located in Appendix I

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REVIEW

Development and validation of the Female Sexual Function Index adaptation for breast cancer patients (FSFI-BC)

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Abstract Sexual dysfunction following breast cancer treatment is common and screening for this is recommended. This study determined the reliability, validity, and acceptability of a breast cancer-specific adaptation of the Female Sexual Function Index, the FSFI-BC. This new measure addresses limitations in the FSFI when assessing sexual dysfunction of women with breast cancer regarding applicability to non-sexually active women, measuring distress and changes after cancer. Female breast cancer survivors ($n = 596$; 429 sexually active, 166 non-sexually active) completed an online survey including demographic/medical information, the FSFI-BC, and scales measuring sexual functioning, fatigue, body image, physical and mental health, and relationship adjustment (Time 1). Three weeks later, 326 women (245 sexually active; 81 non-sexually active) completed the Time 2 survey including the FSFI-BC, and questions regarding its acceptability and perceived change in sexual functioning. Reliability, construct validity, and acceptability were examined using standard scale validation techniques. Exploratory factor analysis delineated seven factors: Changes after cancer, desire/arousal, lubrication, orgasm, pain, satisfaction, and distress, accounting for 79.98 % (sexually active) and 77.19 % (non-active) variance in responses. Acceptable internal consistencies (non-active: $\alpha = 0.71$–0.96; sexually active: $\alpha = 0.89$–0.96) and test–retest reliabilities (non-active: $r = 0.63$–0.86; sexually active: $r = 0.71$–0.88) were evident. Inter-scale correlations provided evidence for convergent and divergent validities of the FSFI-BC. Both sexually active and non-active women provided positive feedback about the FSFI-BC. The optional partner questions demonstrated clinical utility. With desirable psychometric properties and acceptability to participants, the FSFI-BC is suitable for screening for sexual dysfunction in women with breast cancer.

Keywords Breast neoplasms · Sexual dysfunctions (psychological) · Sexual dysfunctions (physiological) · Psychosexual dysfunctions · Questionnaire · DSM-V

Introduction

Breast cancer is the most common female cancer, accounting for 25 % of all cancers worldwide [1]. With 5-year breast cancer survival rates over 80 % [2], there is increased consideration of quality of life issues in these women [3], emphasizing aspects including sexual functioning [4]. Despite women frequently reporting sexual difficulties following breast cancer [5], both women and medical practitioners are hesitant to discuss this topic [6]. Practitioners who initiate conversations about sexual functioning are explicitly giving women permission to talk about this topic [7]. A brief, self-report scale used to screen for sexual dysfunction may be helpful in initiating conversations about sexual difficulties and identifying women who would benefit from additional support in this regard.

Electronic supplementary material The online version of this article (doi:10.1007/s10549-015-3499-8) contains supplementary material, which is available to authorized users.

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Additionally, such a scale could be used to monitor the effects of sexual functioning-focused interventions and breast cancer treatments.

The Female Sexual Function Index (FSFI) [8] has been identified as a promising measure for this purpose [9]. The 19-item FSFI has six subscales (desire, arousal, lubrication, orgasm, pain, satisfaction), with questions addressing aspects of sexual dysfunction, as defined by leading diagnostic systems [10, 11]. It has been validated with varied populations (from healthy women to those with sexual dysfunctions and chronic health problems) including with breast cancer populations [13]. Furthermore, the FSFI was found to be highly relevant and acceptable to women with breast cancer [13]. However, prior research indicates that the FSFI should additionally include items addressing: (1) reasons for sexual dysfunction, including the woman's partner's contribution; (2) the role of artificial lubricants; and (3) the woman's pre-cancer sexual functioning [13].

Concerns have also been raised about the validity of FSFI scores for women who have experienced no recent sexual activity, either with a partner or masturbation [12–14]. In the FSFI, 15 out of 19 items include the '0—No sexual activity' category, but scoring these items for sexually inactive women biases the results towards greater dysfunction, and artificially inflates item variance [12–14]. To date, oncology-focused FSFI validation studies have opted to exclude non-sexually active women [13, 14]. This leads to inevitable loss of information about the functioning of non-active women, which is a major concern in the breast cancer context where a higher percentage (25 %) [13] of women report sexual inactivity than the original FSFI validation study (6.9 %) [8]. Therefore, more appropriate FSFI items for women who report no recent sexual activity are required.

Despite this being necessary for the diagnosis of sexual dysfunction [10, 11], the FSFI neglects to include questions about sexual functioning-specific distress, with most studies reporting distress as a general construct [15]. The FSFI only contains items measuring satisfaction with sexual functioning, which is a related, but distinct construct to distress [16]. Therefore, to make the FSFI more accurate in measuring sexual dysfunction, specific items assessing distress are required.

The aim of this study was to develop and validate an adaptation of the FSFI for breast cancer populations (FSFI-BC). This scale addresses the shortcomings of the FSFI in the breast cancer population by (1) including items relevant to women with no recent sexual activity; (2) assessing sexual functioning-related distress; (3) assessing partner variables; and (4) sexual functioning changes after cancer. The existing lubrication items were also revised to better assess the use of artificial lubricants.

Methods

Study design and participants

Participants were recruited from Breast Cancer Network Australia (BCNA) and Register 4, both Australian consumer support organizations. Invitations to participate in the study, including a link to an online survey, were emailed to members of these organizations. Women who were 18 years of age and had a primary diagnosis of breast cancer (any stage) or ductal carcinoma in situ (DCIS) were eligible to participate. Local institutional human research ethics approval was obtained.

Interested women accessed the online survey and, after providing consent, completed items assessing demographic/medical information, the FSFI-BC, and other measures for demonstrating validity (Time 1). On completion of the Time 1 survey, participants provided an email address if they wished to participate in the second part of the study (Time 2). Two weeks later, interested participants were sent a link to access the Time 2 survey, including the FSFI-BC, and acceptability and change in sexual functioning questions.

Measures

Female Sexual Function Index-Breast Cancer (FSFI-BC) is a 34-item (5- or 6-point Likert-type) scale designed to have 8 subscales: changes after cancer, desire, arousal, lubrication, orgasm, pain, satisfaction, and distress (see Online Resource 1). To aid in clinical interpretation, 4 additional items assessing the partner's role in sexual difficulties were included. Nineteen items (i.e., changes after cancer, desire, satisfaction, and distress subscales) are completed by both sexually active and inactive women, as well as 15 items that separately assess arousal, lubrication, orgasm, and pain (active), and whether difficulties in arousal, lubrication, orgasm, and pain were reasons for sexual inactivity (non-active). Higher scores indicate better sexual functioning. Table 1 contains the comparison between the FSFI and FSFI-BC items.

Several other measures (see Table 2) were administered with the FSFI-BC to establish convergent and divergent validities. All measures have demonstrated acceptable psychometric properties with breast cancer [17–21], chronic illness [22], and general populations [23].

User acceptability was assessed by 4 questions used in prior FSFI research [13] (e.g., 'I felt comfortable answering the questions') rated on a 5-Point Likert-Type Scale ranging from 'strongly disagree' to 'strongly agree.' A mean score over 3 is considered as positive feedback.

Table 1 Comparison between the FSFI-BC and FSFI

Subscale	Comparison between the FSFI and FSFI-BC
Changes after cancer	This subscale is unique to the FSFI-BC
Desire	The FSFI-BC included two identical items from the FSFI
Arousal	**Sexually active women**
	FSFI-BC included four identical items from the FSFI
	Non-sexually active women
	All items assessing arousal for sexually active women were rephrased to assess whether difficulties with a particular aspect of functioning were a reason for inactivity
	E.g., 'How would you rate your level of sexual arousal during sexual activity' was rephrased into 'I did not have sexual activity or intercourse because I experienced a low level of arousal'
Lubrication	**Sexually active women**
	FSFI-BC introduced an additional response category to assess the helpfulness of artificial lubricants in aiding comfort in sexual activity
	E.g., '5 – difficult, but artificial lubricants were helpful'
	Non-sexually active women
	All items assessing lubrication for sexually active women were rephrased to assess whether difficulties with a particular aspect of functioning were a reason for inactivity
	E.g., 'How often did you become lubricated during sexual activity or intercourse' was rephrased into 'I did not have sexual activity or intercourse because I rarely got lubricated'
Orgasm	**Sexually active women**
	FSFI-BC included three identical items from the FSFI
	Non-sexually active women
	All items assessing orgasm for sexually active women were rephrased to assess whether difficulties with a particular aspect of functioning were a reason for inactivity
	E.g., 'How difficult was it for you to reach orgasm' was rephrased into 'I did not have sexual activity or intercourse because I find it difficult to achieve orgasm'
Pain	**Sexually active women**
	FSFI-BC included three identical items from the FSFI
	Non-sexually active women
	All items assessing pain for sexually active women were rephrased to assess whether difficulties with a particular aspect of functioning were a reason for inactivity
	E.g., 'How often did you experience discomfort or pain following vaginal penetration' was rephrased into 'I did not have sexual activity or intercourse because I feel pain after sexual intercourse'
Satisfaction	FSFI-BC included three identical items from the FSFI
	FSFI-BC also included two additional items from the World Health Organization Quality of Life Instrument (WHOQOL-100) [35]
	'How well were your sexual needs fulfilled?'
	'How would you rate your sex life?'
Distress	This subscale is unique to the FSFI-BC
Partner variables	These questions are unique to the FSFI-BC

Statistical analyses

For all measures, mean scores were calculated for participants with less than 20 % missing data [24]. When more than 20 % of data were missing, conservative pair-wise deletion was applied [24].

Internal consistency was calculated using Cronbach's Alpha (acceptable values over 0.70) [25]. Pearson's correlations between Time 1 and Time 2 FSFI-BC subscale scores over 0.70 indicated acceptable test–retest reliability [25]. To ensure that no perceived change in functioning occurred between the two assessment points, women at Time 2 reported whether their desire, arousal, lubrication, orgasm, pain, satisfaction, and distress increased, stayed the same, or decreased between measurements. Test–retest reliability for any subscale was

Table 2 Measures used

Construct	Reason for administration	Scale	Scale structure	Score range and interpretation
Sexual functioning	Convergent validity	The Cancer Rehabilitation Evaluation System (CARES); Sexual Functioning Subscale [17, 18]	4 items applicable to both sexually active and non-active	Total score 0–20
			5-point, Likert-type	Higher score—worse sexual functioning
		Sexual Problems Scale (SPS) [19]	9 items	Total score 9–36
			4-point, Likert-type	Higher score—worse sexual functioning
Body image	Divergent validity	Body Image Scale (BIS) [20]	10 items	Total score 0–30
			4-point Likert-type	Higher score—more severe body image
Fatigue		Fatigue Assessment Scale (FAS) [21]	10 items	Total score 10–50
			5-point Likert-type	Higher score—greater fatigue
Physical and mental health		Medical Outcomes Studies Health Survey (SF-20) [22]	Physical and Mental Health Subscales	Subscale scores 0–1400 (physical health), 0–600 (mental health)
			20 items	
			3-, 5-, 6-point Likert-type	Higher score—better functioning
Relationship adjustment		Revised Dyadic Adjustment Scale (RDAS) [23]	14 items	Total score 0–69
			5-, 6-point Likert-type	Higher score—better adjustment

calculated only for women whose sexual functioning was stable over this period.

Construct validity was reflected by (1) *convergent validity*, as indicated by Pearson's correlations $r \geq 0.30$ between FSFI-BC subscales and other measures of sexual functioning [26–28]; (2) *divergent validity*, as indicated by Pearson's correlations $r \leq 0.30$ between FSFI-BC subscales and measures of fatigue, body image, physical and mental health, and relationship adjustment [26–28], with the magnitude of divergent validity correlations expected to be lower than for convergent validity [29]; and (3) *exploratory factor analysis* (*EFA*), using principal axis factoring with direct oblimin rotation [30], and maximum likelihood estimation, which was appropriate given the observed skewness range: 0.01–1.39 and kurtosis range: 0.12–1.58. The anticipated eight factors were extracted and scree plots examined. The acceptable solution should account for 70–80 % of variance [30].

Statistical significance was set to $\alpha = 0.05$. All analyses were conducted using the SPSS (Version 22, Armonk, NY: IBM Corp).

Results

Of the 726 women responding to the study invitation, 3 (0.4 %) declined consent, and 127 (17.5 %) did not complete the survey, leaving an analyzable Time 1 sample of 596 [429 (72 %) currently sexually active; 166 (28 %) no recent sexual activity; see Table 3]. Sexually active women were more likely to have a partner ($\chi^2 = 6.05$, d.f. $= 1$, $p = 0.01$); have higher education ($\chi^2 = 6.43$, d.f. $= 2$, $p = 0.04$); be pre-menopausal ($\chi^2 = 6.96$, d.f. $= 1$, $p < 0.01$), younger ($t = 3.55$, d.f. $= 593$, $p < 0.01$), and diagnosed with breast cancer more recently ($t = 2.06$, d.f. $= 589$, $p = 0.04$); and have a better body image ($t = 2.54$, d.f. $= 593$, $p = 0.01$), less fatigue ($t = 3.79$, d.f. $= 593$, $p < 0.01$), better physical ($t = -4.15$, d.f. $= 593$, $p < 0.01$), and mental health ($t = -4.98$, d.f. $= 593$, $p < 0.01$); better relationship adjustment ($t = -6.83$, d.f. $= 495$, $p < 0.01$) and sexual functioning [Sexual Problems Scale—SPS ($t = 3.97$, d.f. $= 569$, $p < 0.01$); Cancer Rehabilitation Evaluation System—CARES ($t = 10.15$, d.f. $= 565$, $p < 0.01$)].

Of the 596 Time 1 completers, 508 (85 %) provided email addresses to participate in the Time 2 survey. Generally, these women did not differ from women who did not provide their emails on demographic variables, levels of fatigue, body image, physical and mental health, relationship adjustment, and most sexual functioning variables as measured by the FSFI-BC (all $p > 0.05$). However, the women who provided their email addresses to participate in the Time 2 survey were found to be more distressed about their level of sexual functioning ($t = 2.55$, d.f. $= 585$, $p = 0.01$). Of the women who provided their email addresses, 346 (68 %) responded to the invitation. Of

Table 3 Demographic Information

	Sexually active ($n = 429$)		Sexually inactive ($n = 166$)	
	No.	%	No.	%
Country of birth				
Australia	340	79.3	128	77.1
Other countries	89	20.7	38	22.9
Relationship status				
Partnered	369	86.0	129	77.7
Single	60	14.0	37	22.3
Children				
Yes	348	81.1	130	78.3
No	79	18.4	31	18.7
Missing	2	0.5	5	3
Age				
Mean	54.48		57.5	
SD	9.32		8.71	
Education				
High school or less	84	19.6	49	29.5
College or some university	141	32.9	54	32.5
Bachelor's degree	106	24.7	26	15.7
Postgraduate studies	98	22.8	37	22.3
Employment				
Employed	280	65.3	90	54.2
Unemployed	31	7.2	13	7.8
Retired	118	27.5	60	36.2
Missing	0	0	3	1.8
Diagnosis				
DCIS	114	26.6	37	22.3
Early stage breast cancer	282	65.7	106	63.9
Metastatic breast cancer	21	4.9	15	9.0
Missing	12	2.8	8	4.8
Time since diagnosis				
Mean (years)	4.76		5.65	
SD	4.65		4.85	
Surgery type				
Lumpectomy/wide local excision	197	45.9	74	44.6
Single mastectomy	146	34.0	53	31.9
Double mastectomy	85	19.8	38	22.9
Missing	1	0.2	1	0.6
Adjuvant therapies				
Ever received				
No treatment	40	9.3	15	9.0
Hormone, radiation OR chemotherapy only	88	20.5	47	28.3
Two or more therapies	301	70.2	104	62.7
Currently receiving				
No treatment	196	45.7	77	46.4
Hormone, radiation OR chemotherapy	230	53.6	86	51.8
Two or more therapies	3	0.7	3	1.8
Current menopausal status				
Pre-menopausal	76	17.7	15	9.0
Postmenopausal	353	82.3	151	91

those, 1 (0.3 %) did not provide consent and 19 (5.5 %) did not complete the survey, leaving 326 (94.2 %) Time 2 participants whose data were analyzed [245 (75.2 %) sexually active; 81 (24.8 %) no recent sexual activity]. The Time 2 survey was completed on average 17.89 (SD = 18.25) days after Time 1.

FSFI-BC for non-sexually active women

Factorial structure

FSFI-BC items were sufficiently inter-correlated ($\chi^2 = 4559.61$, d.f. = 561, $p < 0.01$) and sampled [KMO ranged 0.73–0.90, apart from item 5 (KMO = 0.48) and item 7 (KMO = 0.45)] to warrant EFA. Table 4 contains loadings and eigenvalues for the 8 factors (accounting for 77.19 % of variance in responses): changes after cancer (split into two factors), desire/reason for inactivity-arousal, reason for inactivity-lubrication, reason for inactivity-orgasm, reason for inactivity-pain, satisfaction, and distress. The obtained factor structure was as anticipated, apart from changes after cancer items 5 and 7 loading onto a separate factor, and desire and arousal items loading onto a single factor. For simplicity, items 5 and 7 were removed from further analysis and desire and reason for inactivity-arousal items were combined into a single factor.

Reliability

Internal consistencies of the final subscales (see Table 5) were acceptable, ranging from 0.71 (satisfaction) to 0.97 (reason for inactivity—lubrication). Most test–retest reliabilities were acceptable, ranging from 0.72 (desire/reason for inactivity-arousal and reason for inactivity-lubrication) to 0.86 (satisfaction). Reason for inactivity-orgasm subscale had test–retest reliability of 0.63.

Validity

The pattern of inter-scale correlations with other measures of sexual functioning (CARES and SPS) provided evidence of convergent validity (Table 5). Higher FSFI-BC correlations with SPS than CARES were noted, as CARES items focus on sexual attractiveness and interest only, and SPS measures sexual functioning more broadly. Correlations between SPS and subscales of FSFI-BC were moderate to high (absolute range 0.37–0.60), as expected. With the exception of correlations between relationship adjustment and FSFI-BC satisfaction ($r = 0.46$), body image and FSFI-BC distress ($r = -0.36$) and body image and FSFI-BC changes after cancer ($r = -0.31$), all other correlations between the FSFI-BC subscales and measures of body image, fatigue, physical health, mental health and relationship adjustment were below 0.30, as expected (see Table 5). Furthermore, for all subscales, correlations associated with convergent validity were higher than for divergent validity.

Acceptability to patients

Overall, the women provided positive feedback about the FSFI-BC, as they reported (1) feeling comfortable answering questions ($M = 4.01$, SD = 0.87), and that (2) the questions were easy to complete ($M = 3.81$, SD = 0.91) and relevant to their experiences ($M = 3.43$, SD = 1.18); and (3) the questionnaire was about the right length ($M = 4.23$, SD = 0.68).

Qualitative reasons for not being sexually active

One hundred and twenty women provided additional information about reasons for not being sexually active. The most common reasons were no partner (23 %), no sexual interest (21 %), and partner's difficulties with sexual functioning, especially low interest and erectile dysfunction (19 %), all areas that are covered in the FSFI-BC.

FSFI-BC for sexually active women

Factorial structure

With sexually active women, Bartlett's test of sphericity was significant ($\chi^2 = 12334.26$, d.f. = 528, $p < 0.01$) and all items were sufficiently sampled (KMO ranged 0.65–0.97), indicating that the EFA was appropriate. Table 6 contains factor loadings and eigenvalues for the 8 factors that emerged (accounting for 79.78 % of variance response scores): changes after cancer (split into two factors), desire/arousal, arousal/orgasm, lubrication, pain, satisfaction, and distress. Again, the emergent factor structure was as anticipated and almost identical to the FSFI-BC for non-sexually active women, apart from (1) arousal items loading onto both desire and orgasm subscales; and (2) some distress items (orgasm, pain, overall sex life) having minor but significant (>0.4) loadings onto corresponding factors (orgasm, pain, satisfaction), as well as larger loadings on the distress factor. Again, items 5 and 7 loaded on a separate factor. Consequently, items 5 and 7 were removed from further analysis and all Arousal items were combined with desire items as consistent with the structure of the FSFI-BC for non-sexually active women.

Reliability

Table 5 provides evidence for excellent internal consistency for all of the scales (range 0.86–0.96) and acceptable test–retest reliability (range 0.71–0.88).

Table 4 EFA results—non-sexually active participants

Factors	RL	D	C	RP	S	D/RA	RO	C(2)
1. Changes after cancer—desire			0.86					
2. Changes after cancer—arousal			0.97					
3. Changes after cancer—lubrication			0.72					
4. Changes after cancer—orgasm			0.77					
5. Changes after cancer—pain								0.80[a]
6. Changes after cancer—satisfaction			0.46					
7. Changes after cancer—distress								0.71[a]
8. Desire/interest frequency						0.79		
9. Level (degree) of desire/interest						0.76		
SN1 RFI—low frequency of arousal						0.70		
SN2 RFI—low level of arousal						0.50		
SN3 RFI—low confidence in ability to get aroused						0.41		
SN4 RFI—low satisfaction about the level of arousal						0.48		
SN5 RFI—low frequency of lubrication	0.75							
SN6 RFI—difficulty in becoming lubricated	0.68							
SN7 RFI—did not maintain lubrication	0.89							
SN8 RFI—difficulty maintaining lubrication	0.85							
SN9 RFI—Low frequency of orgasms							−0.87	
SN10 RFI—difficulty achieving orgasms							−0.89	
SN11 RFI—low satisfaction with orgasms							−0.85	
SN12 RFI—pain during intercourse				0.83				
SN13 RFI—pain following intercourse				0.86				
SN14 RFI—intense and severe pain				0.81				
SN15 RFI—low satisfaction with emotional closeness					0.44			
10. Satisfaction with sexual relationship					0.45			
11. Satisfaction with overall sexual life					0.64			
12. Degree sexual needs fulfilled					0.61			
13. Overall sex life rating					0.68			
14. Distress—desire		0.92						
15. Distress—arousal		0.96						
16. Distress—orgasm		0.81						
17. Distress—lubrication		0.89						
18. Distress—pain		0.75						
19. Distress—overall sex life		0.80						
Eigen values	10.29	3.84	2.97	2.15	2.04	1.87	1.33	1.26

RFI reason for inactivity, *RL* reason for inactivity-lubrication, *D* distress, *C* changes after cancer, *RP* reason for inactivity—pain, *S* satisfaction, *D/RA* desire/reason for inactivity—arousal, *RO* reason for inactivity—orgasm, *SN* items applicable only to non-sexually active women

Only loadings >0.40 were shown in table

[a] Did not load on expected factor

Validity

FSFI-BC subscales were moderately inter-correlated. Convergent validity was evidenced by moderate to high correlations (absolute range 0.34–0.76) with other measures of sexual functioning (CARES and SPS; see Table 5), again with higher correlations between SPS and FSFI-BC. With the exception of correlations between relationship adjustment and FSFI-BC satisfaction ($r = 0.46$), and mental health and FSFI-BC satisfaction ($r = 0.32$), all other correlations between the FSFI-BC subscales and measures of body image, fatigue, physical health, mental health, and relationship adjustment were 0.30 or below, as expected (see Table 5). Furthermore, for all subscales, correlations associated with convergent validity were higher than for divergent validity.

Table 5 FSFI-BC for both non-sexually active and sexually active women: Internal consistency, test–retest reliability, score ranges, means, and standard deviations, convergent and divergent validity

	Non-sexually active women							Sexually active women						
	C	D/RA	RL	RO	RP	S	D	C	D/A	L	O	P	S	D
Internal consistency														
Time 1	0.88	0.81	0.97	0.96	0.92	0.71	0.95	0.86	0.93	0.90	0.92	0.96	0.89	0.91
Time 2	0.90	0.81	0.97	0.98	0.90	0.72	0.94	0.88	0.94	0.87	0.92	0.94	0.90	0.91
Test–retest reliability	0.83	0.72	0.72	0.63	0.77	0.86	0.77	0.83	0.88	0.71	0.85	0.80	0.86	0.77
Score ranges	5–25	6–30	4–20	3–15	3–15	5–25	6–30	5–25	6–30	4–24	3–15	3–15	5–25	6–30
Subscale means (SD)	7.89 (3.60)	11.30 (4.46)	10.42 (4.75)	7.97 (3.74)	8.78 (3.62)	9.41 (3.97)	22.55 8.24	9.40 (3.89)	15.97 (6.72)	15.78 (6.51)	9.59 (4.30)	10.09 (5.20)	14.81 (5.95)	21.17 (7.28)
Subscale correlations[a]														
C	1.00							1.00						
D/RA	0.47*	1.00						0.58*	1.00					
RL	0.33*	0.46*	1.00					0.43*	0.61*	1.00				
RO	0.34*	0.42*	0.56*	1.00				0.46*	0.72*	0.55*	1.00			
RP	0.35*	0.35*	0.56*	0.38*	1.00			0.34*	0.45*	0.51*	0.28*	1.00		
S	0.24*	0.30*	0.30*	0.28*	0.29*	1.00		0.32*	0.55*	0.47*	0.43*	0.49*	1.00	
D	0.32*	0.31*	0.38*	0.25*	0.26*	0.31*	1.00	0.55*	0.53*	0.39*	0.47*	0.44*	0.39*	1.00
Convergent validity[a]														
CARES	−0.25*	−0.29*	−0.24*			−0.39*	−0.32*	−0.38*	−0.47*	−0.35*	−0.34*	−0.35*	−0.62*	−0.36*
SPS	−0.47*	−0.49*	−0.47*	−0.45*	−0.37*	−0.52*	−0.60*	−0.58*	−0.67*	−0.45*	−0.61*	−0.42*	−0.56*	−0.76*
Divergent validity[a]														
FAS		−0.18	−0.18				−0.25*	−0.21*	−0.27*	−0.17*	−0.24*	−0.20*	−0.29*	−0.24*
BIS	−0.31*	−0.22*				−0.28*	−0.36*	−0.29*	−0.18*	−0.16*	−0.18*	−0.18*	−0.30*	−0.26*
MOS-PH				0.19			0.18	0.14*	0.15*		0.13*	0.14*	0.24*	0.19*
MOS-MH		0.16				0.28*	0.26*	0.18*	0.21*	0.17*	0.21*	0.12	0.32*	0.23*
RDAS	0.22	0.18				0.46*		0.11	0.23*	0.20*	0.11	0.22*	0.46*	0.12

C changes due to cancer, *D/RA* desire/reason for inactivity-arousal, *RL* reason for inactivity-lubrication, *O* reason for inactivity-orgasm, *P* reason for inactivity-pain, *S* satisfaction, *D* distress, *D/A* desire/arousal, *L* lubrication, *O* orgasm, *P* pain, *FAS* Fatigue Assessment Scale, *BIS* Body Image Scale, *MOS-PH* Medical Outcomes Study Physical Health Subscale, *MOS-MH* Medical Outcomes Study Mental Health Subscale, *RDAS* Revised Dyadic Adjustment Scale

* $p < 0.01$

[a] Only values significant at 0.05 level were shown

Table 6 EFA results—sexually active participants

Factors	A/O	S	P	D	C	L	C(2)	D/A
1. Changes with cancer—desire					0.70			
2. Changes with cancer—arousal					0.83			
3. Changes with cancer—lubrication					0.62			
4. Changes with cancer—orgasm					0.63			
5. Changes with cancer—pain							0.84	
6. Changes with cancer—satisfaction					0.57			
7. Changes with cancer—distress							0.60	
8. Desire/interest frequency								−0.81
9. Level (degree) of desire/interest								−0.81
SA1 Frequency of arousal								−0.49
SA2 Level of arousal	0.41[a]							−0.49
SA3 Confidence in becoming sexually aroused	0.45[a]							
SA4 Satisfaction with arousal	0.54[a]							
SA5 Frequency of lubrication						0.66		
SA6 Difficulty in getting lubricated						0.81		
SA7 Ability to maintain lubrication						0.86		
SA8 Difficulty in maintaining lubrication						0.83		
SA9 Frequency of orgasm	0.82							
SA10 Difficulty in achieving orgasm	0.75							
SA11 Satisfaction in the ability to reach orgasm	0.77							
SA12 Frequency of pain during intercourse			0.90					
SA13 Frequency of pain following intercourse			0.86					
SA14 Degree of severity of pain			0.95					
SA15 Satisfaction with emotional closeness during sexual activity		0.74						
10. Satisfaction with sexual relationship		0.79						
11. Satisfaction with overall sexual life		0.65						
12. Degree sexual needs fulfilled		0.50						
13. Overall sex life rating		0.62						
14. Distress—desire				−0.79				
15. Distress—arousal				−0.83				
16. Distress—orgasm	0.44[a]			−0.59				
17. Distress—lubrication				−0.65				
18 Distress—pain			0.46[a]	−0.53				
19. Distress—overall sex life		0.41[a]		−0.71				
Eigen values	14.03	2.97	2.63	2.11	1.90	1.28	1.23	0.98

A/O arousal/orgasm, *S* satisfaction, *P* pain, *D* distress, *C* changes after cancer, *L* lubrication, *D/A* desire/arousal, *SA* items applicable only to sexually active women

Only loadings >0.40 were shown in table

[a] Did not load on expected factor

Acceptability to patients

Again, the women provided positive feedback about the FSFI-BC, as they reported (1) feeling comfortable answering questions ($M = 4.20$, SD = 0.80), and that (2) the questions were easy to complete ($M = 4.07$, SD = 0.80) and relevant to their experiences ($M = 3.96$, SD = 0.94); and (3) the questionnaire was about the right length ($M = 4.22$, SD = 0.65).

Additional partner items

The 4 items assessing the impact partner variables had on sexual functioning were significantly inter-correlated (range: $r = 0.27$–0.48, $p < 0.01$; Table 7), indicating that they measure related but different constructs. Women reported that their sexual functioning was influenced by their partner's desire for sex (44 %), availability of a partner (30 %), the partner's sexual problems (15 %), and

Table 7 Partner variables

	C8 the availability of partner	C9 my partner's desire for sex	C10 my partner's sexual problems	C11 my partner's response to my body after the breast cancer or treatment
C8	1.00			
C9	0.31*	1.00		
C10	0.28*	0.40*	1.00	
C11	0.27*	0.31*	0.48*	1.00
RDAS			−0.24*	−0.33*

Only values significant at 0.05 values are shown

RDAS Revised Dyadic Adjustment Scale

* Significant at $p = 0.01$

the partner's response to the woman's body changes after breast cancer and treatment (14 %), indicating the clinical utility of these items in further exploring reasons for reported sexual difficulties.

Discussion

The purpose of this study was to develop and validate an adaptation of the FSFI specifically designed for screening sexual dysfunction in women with breast cancer (FSFI-BC). The FSFI-BC introduces the changes after cancer and distress subscales beyond the original FSFI, and contains items applicable to women who are not sexually active, as well as retaining the original items for women who report recent sexual activity. Overall, the FSFI-BC contains 7 subscales, with 3 subscales applicable to both sexually active and inactive women (changes after cancer, satisfaction, distress) and 4 subscales separately applicable to sexually active (desire/arousal, lubrication, orgasm, pain) and non-active (desire/reasons for inactivity-arousal, reasons for inactivity-lubrication, reasons for inactivity-orgasm, reasons for inactivity-pain) women. Additionally, the FSFI-BC introduces a separate set of 4 items that explore the partner's contribution to the reported sexual functioning. These items do not contribute to the FSFI-BC scores, but can be used to aid in clinical interpretations of these scores.

Both sexually active and non-active women provided positive feedback about the items in the FSFI-BC, which is important given the sensitive nature of these questions. The results also indicate that the FSFI-BC has excellent psychometric properties, with evidence of internal consistency, test–retest reliability along with both convergent and divergent validity. The factorial structure that emerged through the EFA was almost identical in the two versions of the FSFI-BC for non-sexually active and sexually active women, providing evidence for the robustness of the extracted factors. The only exception was the desire and arousal items loading on the same factor (both sexually active and non-active participants), and some arousal and orgasm items loading on the same factor in the sexually active group. Desire and arousal items have loaded onto a single factor in all previous FSFI validation studies [8, 12, 31], and some cross loading between arousal and orgasm items has been observed [8, 12]. For the FSFI-BC, it was decided to create a single factor from the desire and arousal items to be consistent with the current conceptualizations indicating that it is difficult to distinguish between desire and arousal in females [10].

These findings demonstrate that the FSFI-BC has favorable psychometric properties and is acceptable for use by women with breast cancer, irrespective of whether or not they are currently sexually active. The FSFI-BC is, therefore, eminently suited for routine administration to screen for sexual dysfunction in clinical and research settings. The measure is simple to administer and score, and is suitable for use by health and allied health professionals as a screening tool. As the FSFI-BC is a self-report scale, it will take no additional practitioner time to administer and only 5 minutes to score, which is important for busy clinical practices. As participants in this study reported that the questionnaire is about the right length, patient burden is unlikely.

As a newly developed scale, the clinical cut-off scores for the FSFI-BC are yet to be developed. Clinical interpretation guidelines for the FSFI-BC are provided in Online Resource 1. Using these clinical guidelines, it can be seen that while the majority of women experience deterioration in sexual functioning after cancer, they may not be significantly bothered or distressed about this (see Table 5), which is consistent with findings from other studies [32–34]. This also highlights the importance of assessing levels of distress in addition to sexual functioning, as women experiencing sexual difficulties may not necessarily be distressed about this. Additionally, it is apparent that difficulties in desire, arousal, lubrication, orgasm, and pain are all important contributors to sexual inactivity in women.

It is recommended that the partner items are not summed, but considered individually when interpreting other

scores of the FSFI-BC. Any score of 4 or higher indicates that partner variables may significantly impact on the woman's reported sexual functioning. The finding that two out of three most frequently cited reasons for lack of sexual activity included partner's availability and sexual difficulties highlights the importance of assessing the partner's role in reported sexual functioning. Additionally, having a better understanding of the aspects contributing to the sexual dysfunction may lead to more appropriate treatment (e.g., individual or couple interventions).

These results need to be considered with the following limitations in mind. Although the sample size was adequate for the statistical analyses conducted, the participants self-selecting may have introduced bias. The women who indicated willingness to participate in the second part of the survey were found to be more distressed about their sexual functioning than the women who declined participation, which could also bias the results. Additionally, the majority of participants were Australian-born women, which may limit generalizability of the results to other cultures, especially from non-English speaking developing countries. Our sample contained women with breast cancer and DCIS, regardless of stage or disease or treatment received, although most of these women were well educated and had internet access.

In conclusion, the FSFI-BC is a screening scale for sexual dysfunction that has been developed to be specifically applicable to women with breast cancer. The findings of the present study support the use of this measure with breast cancer patients, whether or not they are sexually active. Clinicians and researchers will be able to assess any perceived changes in functioning after cancer diagnosis and treatment as well as levels of distress experienced due to sexual difficulties. The latter is important in diagnosing sexual dysfunction and identifying women who would benefit from additional treatment. Most importantly, the FSFI-BC can be used to give women and professionals the permission to raise the subject of sexual functioning in clinical consultations.

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Compliance with ethical standards

Conflict of interest None.

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Chapter 5: General Discussion

Sexual difficulties following breast cancer diagnosis and treatment are both prevalent and pervasive (Kedde et al., 2013; Panjari et al., 2011; Pumo et al., 2012), and can have a significant impact on a woman's mental health and her relationships (Arrington et al., 2004; Jeffery et al., 2009). Unfortunately, there are a number of barriers to discussing and addressing sexual functioning for both the women with breast cancer themselves and their practitioners (Bober & Varela, 2012; Hodkinson, 2008). A woman's sexual difficulties may remain unrecognised and she may not gain access to appropriate support (Hodkinson, 2008). Evidence-based treatments for sexual dysfunction in women with breast cancer exist (Krychman & Katz, 2012), so it is important that the women requiring this additional support are identified.

An appropriate, routinely administered scale screening for sexual dysfunction may be able to overcome this some barriers to open communication, as it may be used: (1) to identify women that would benefit from additional support; and, (2) as a 'conversation starter', giving both women and practitioners permission to discuss sexual difficulties. However, in the absence of one 'gold standard' measure, there have been numerous scales used in the literature, so for a health professional to decide upon about the most appropriate scale may be difficult (Bartula & Sherman, 2013).

This thesis aimed to identify an appropriate a scale that screens for sexual dysfunction in women diagnosed with breast cancer. This scale would need to be simple enough to be routinely administered by various professionals with whom the women will consult during their cancer journey. The measure also needs to be regarded as appropriate by the women themselves, and to be psychometrically reliable and valid when used with this population. To meet this objective, this thesis includes a systematic review and two empirical studies. The systematic review was conducted to identify the best available scale that has been used to assess sexual dysfunction within the breast cancer context (Chapter 2). This was followed by two empirical studies (Chapters 3 and 4) which validated and further developed the Female Sexual Function Index – FSFI (Rosen et al., 2000), one of the preferred measures identified by the systematic review. This final chapter aims to summarise the specific objectives and outcomes of the systematic review and empirical studies and synthesise the results in the context of the existing literature.

5.1 Summary of the Main Findings

The systematic review (Chapter 2) aimed to identify the scale that had superior psychometric properties, which also covered the main areas of sexual dysfunction as identified by the leading international diagnostic systems (American Psychiatric Association, 2013; World Health Organization, 2004): desire, arousal, orgasm, pain and distress. Published studies

reporting on sexual functioning in breast cancer were reviewed from 1992-2013 to identify the scales used to measure sexual functioning. Overall, 30 scales were identified, 18 were designed to specifically assess sexual functioning and 12 were the subscales of broader, quality of life measures. Each scale was thoroughly reviewed and assigned a score, reflecting the quality of psychometric properties and the extent to which it assesses the areas of sexual dysfunction.

Although no scales received full scores, the FSFI (Rosen et al., 2000) was identified as the highest-scoring measure, closely followed by the Sexual Problems Scale – SPS (Perez et al., 2010) and Arizona Sexual Experience Scale – ASEX (McGahuey et al., 2000). In general, many scales lacked validation in the breast cancer context and evidence of convergent validity, as well as lacking questions about the levels of distress experienced as a result of sexual difficulties, an important construct differentiating between sexual problems and dysfunction (American Psychiatric Association, 2013; World Health Organization, 2004). The systematic review concluded that, in the absence of the 'gold standard', any of the three top scoring scales could be used in research and clinical practice, as long as the authors were aware of the limitations: psychometric properties in breast cancer population were lacking (FSFI, ASEX), no test-retest data (SPS), no measure of distress (FSFI, ASEX, SPS), and no measure of pain (ASEX).

The FSFI is a widely used scale in breast cancer research with adequate general psychometric properties, yet it lacked validation data for use in this context. Therefore, the aim of the first empirical study (Chapter 3) was to thoroughly examine psychometric properties of this scale with women diagnosed with breast cancer. Additionally, consistent with the general aims of the thesis, the level of acceptability of the questions to women with breast cancer was examined, an aspect that was lacking from all previous FSFI validation studies in any context. .

With the adequate sample of 399 sexually active women with breast cancer, the FSFI showed excellent psychometric properties, with evidence of internal consistency, test-retest reliability, convergent, divergent and discriminant validities. The confirmatory factor analysis provided evidence for the anticipated subscale structure. The women completing the questionnaire felt comfortable answering the questions, found the questions easy to answer, relevant to their experiences, and about the right length. In general, the evidence from this study suggested that the FSFI could be confidently used with the sexually active women with breast cancer. The results cautioned about the validity of the total score and the usefulness of item 14 (enquiring about the level of emotional closeness with the partner). Furthermore, the feedback from the participants indicated that although they found the FSFI acceptable, they thought that it could be further improved by adding questions to assess: (1) reasons for sexual dysfunction;

(2) the contribution of partner's factors to the reported sexual difficulties; (3) the effectiveness of artificial lubricants; and, (4) the woman's pre-cancer sexual functioning.

Although the original FSFI showed excellent psychometric properties and adequate acceptability, the weaknesses commonly reported in the literature were not addressed in our first empirical study: the difficulty in using the FSFI with women that did not experience recent sexual activity (Baser, Li, & Carter, 2012; Brotto, 2009; Meyer-Bahlburg & Dolezal, 2007) and the absence of items measuring distress (Bartula & Sherman, 2013; Forbes, Baillie, & Schniering, 2014). The second empirical study (Chapter 4) aimed to address these concerns, as well as to include the improvements suggested by the participants in the first empirical study. This resulted in the development of the Female Sexual Function Index – Breast Cancer adaptation (FSFI-BC), which was validated on 596 women diagnosed with breast cancer. The FSFI-BC has a separate set of questions that non-sexually active women can answer to ascertain the reasons for absence of sexual activity. Additionally, items measuring distress and change after cancer have been included, as well as questions enquiring about the partner's role in reported sexual difficulties.

The FSFI-BC has been shown to have excellent psychometric properties, with acceptable internal consistency, test-retest reliability, and convergent and divergent validities. The exploratory factor analysis provided evidence for seven subscales: changes after cancer, desire/arousal, lubrication, orgasm, pain, satisfaction and distress. Again, the participants provided positive feedback about the scale, which was reported to be easy to complete, relevant to experiences, about the right length (despite of the increase in the number of items following the addition of items assessing changes after cancer, distress and partner variables). Additionally, the participants reported that they felt comfortable answering the questions. Therefore, there is preliminary evidence that the FSFI-BC is a valid, reliable and acceptable scale for screening for sexual dysfunction in women with breast cancer that has addressed long-standing criticisms of the original FSFI.

5.2 Relationship of the Findings with the Previous Research

5.2.1 Female Sexual Function Index (FSFI)

The original FSFI has been previously validated on healthy women (Rosen et al., 2000; Wiegel, Meston, & Rosen, 2005), women diagnosed with sexual arousal disorders (Rosen et al., 2000; Wiegel et al., 2005), female orgasmic disorders (Meston, 2003; Wiegel et al., 2005), sexual desire disorders (Meston, 2003; Wiegel et al., 2005), multiple sexual disorders (Wiegel et al., 2005), gynaecological cancer (Baser et al., 2012), vulvar intraepithelial neoplasia (Likes,

Stegbauer, Hathaway, Brown, & Tillmanns, 2006), vulvodonia (Masheb, Lozano-Blanco, Kohorn, Minkin, & Kerns, 2004) and chronic pelvic pain (Verit & Verit, 2007).

The results of the FSFI validation on the women diagnosed with breast cancer (Chapter 3) are consistent with these previous studies. In particular, internal consistency was found to be adequate, with the trend towards the satisfaction subscale having the lowest internal consistency and lubrication the highest, which was identical to the pattern observed in other populations (Baser et al., 2012; Likes et al., 2006; Masheb et al., 2004; Meston, 2003; Rosen et al., 2000; Wiegel et al., 2005). The test-retest reliability of the FSFI for the breast cancer population was adequate and consistent with previous studies (Rosen et al., 2000; Verit & Verit, 2007), with the exception of the arousal, orgasm and pain subscales in women with arousal disorders (Rosen et al., 2000). Additionally, the literature to date has not been able to consistently identify subscales with the highest, or indeed the lowest test-retest reliability (Bartula & Sherman, 2015; Rosen et al., 2000; Verit & Verit, 2007).

The confirmatory factor analysis (CFA) provided evidence for calculation of all six factors: desire, arousal, orgasm, lubrication, pain and satisfaction, which is consistent with previous CFA results (Opperman, Benson, & Milhausen, 2013). In our study, the second-order model (involving the 'total') did not provide an adequate fit to these data. In the Opperman et al. (2013) study the second-order model, although inferior to the first order model (no total), was still adequate. Additionally, in the present study of the breast cancer population, item 14 (regarding the level of emotional closeness with the partner) did not fit the model as expected. Lastly, the CFA results from both Opperman et al. (2013) and our studies were different from the previous factor analytic studies that used exploratory factor analysis (Baser et al., 2012; Forbes et al., 2014; Rosen et al., 2000; Wiegel et al., 2005), where desire and arousal formed a single factor.

The subscales of the FSFI in the present research had low to moderate correlations with body image, fatigue, impact of cancer, physical functioning, depression, anxiety, and relationship adjustment, providing evidence for divergent validity. This is consistent with previous research, which found similar correlations with marital adjustment (Baser et al., 2012; Meston, 2003; Rosen et al., 2000; Wiegel et al., 2005), depression, impact of cancer, menopausal symptoms, reproductive concerns, quality of life and functional health (Baser et al., 2012). Convergent validity of the FSFI in the breast cancer context was evidenced by moderate to high correlations with other measures of sexual functioning. This is the first reported study of convergent validity of the FSFI in any context.

All FSFI subscales apart from orgasm were able to discriminate between women with breast cancer currently receiving treatment and those who were treatment free. The FSFI's discriminant ability in the breast cancer context appears better than in the gynaecological cancer context, as for that population only lubrication and pain subscales were able to demonstrate significant differences between women on treatment and those that were treatment free (Baser et al., 2012). Additionally, previous studies have indicated that the FSFI subscales were able to discriminate between women with sexual dysfunctions and healthy controls (Meston, 2003; Rosen et al., 2000; Wiegel et al., 2005), those that have undergone vulvar excisions and women that have not [all but pain subscale (Likes et al., 2006)], women reporting chronic pelvic pain and healthy controls (Masheb et al., 2004).

5.2.2 Female Sexual Function Index, Breast Cancer Adaptation (FSFI-BC)

As the FSFI-BC is an adaptation of the original FSFI it was encouraging to observe that the psychometric properties remained robust. The internal consistency and test-retest reliabilities were acceptable, consistent between versions of the FSFI-BC for the sexually active and non-active women, as well as in line with what was observed with the original FSFI scale (Baser et al., 2012; Likes et al., 2006; Masheb et al., 2004; Meston, 2003; Rosen et al., 2000; Verit & Verit, 2007; Wiegel et al., 2005).

Exploratory factor analysis (EFA) identified seven subscales: changes after cancer, desire/arousal, lubrication, orgasm, pain, satisfaction and distress. The newly-created items assessing changes after cancer and distress formed separate factors, as expected. The remainder of the subscales (desire/arousal, lubrication, pain and satisfaction) showed consistent loadings between non-sexually active and sexually active groups. This was consistent with the other EFA studies of the original FSFI (Baser et al., 2012; Forbes et al., 2014; Rosen et al., 2000; Wiegel et al., 2005), but differed from the confirmatory factor analyses which were able to separate desire and arousal items (Bartula & Sherman, 2015; Opperman et al., 2013). To be consistent with the diagnostic literature (American Psychiatric Association, 2013), it was decided to combine desire and arousal subscales.

There was evidence for convergent and divergent validity of the FSFI-BC, with generally larger correlations with sexual functioning measures (convergent validity) than measures of fatigue, body image, mental and physical health and relationship adjustment (divergent validity). The pattern of correlations was similar between sexually-active and non-active versions of the FSFI-BC, as well as the original FSFI's validation on women diagnosed with breast cancer (Bartula & Sherman, 2015).

5.2.3 Relationship with the other sexual functioning scales

In Chapter 2 all scales used in breast cancer research from 1992-2013 were reviewed by assigning a score indicating the extent to which they meet psychometric criteria, as well as covering the areas of sexual dysfunction as defined by the international diagnostic systems (American Psychiatric Association, 2013; World Health Organization, 2004). The total score any scale could obtain was 17, where up to 12 points were awarded for psychometric properties and 5 for diagnostic coverage.

Prior to the empirical studies undertaken in the present thesis, the review indicated that the FSFI was a leading scale, with 11 points, closely followed by the Sexual Problems Scale – 10.5 points (Perez et al., 2010) and Arizona Sexual Experiences Scale – 10 points (McGahuey et al., 2000). As can be seen from the Table 5.1 (below), the first empirical study has increased the FSFI's score to 13. The FSFI-BC's score, following the second empirical study is now 14.

Table 5.1: Scores obtained for psychometric properties and DSM-5/ICD-10 coverage following first empirical study (FSFI) and second empirical study (FSFI-BC)

Scale	Validation Sample	Reliability	Content Validity	Criterion Validity	Construct Validity	Responsiveness to change	DSM-5/ICD-10	Total Score
FSFI	2	2	1	0	4	0	4	13
FSFI-BC	2	2	1	0	4	0	5	14

5.2.4 Scales measuring sexual dysfunction in women who are not sexually active

Our empirical studies have indicated that as many as 25% of women with breast cancer report no recent sexual activity. These women are often neglected in the literature using the original FSFI, due to limitations of this measure mentioned earlier. In fact, a number of the FSFI validation studies have specifically excluded women who report being sexually inactive (Bartula & Sherman, 2015; Baser et al., 2012; Meston, 2003; Rosen et al., 2000; Wiegel et al., 2005). Furthermore, in the breast cancer literature sexually inactive women are either excluded (Alder et al., 2008; Can et al., 2008; Ebrahimi et al., 2015; Farah, Shahram, & Zeinab, 2014; Harirchi, Montazeri, Zamani Bidokhti, Mamishi, & Zendehdel, 2012; Sbitti et al., 2011) or their FSFI scores are calculated (Pumo et al., 2012; Raggio, Butryn, Arigo, Mikorski, & Palmer, 2014; Schover et al., 2011; Speer et al., 2005) despite the concerns about the validity of these scores (Meyer-Bahlburg & Dolezal, 2007). This may limit the knowledge we have about this group of women.

To the authors' knowledge, the FSFI-BC is only one of two scales that contains questions specifically designed for the women who are not sexually active, the other scale being the Sexual Activity Questionnaire - SAQ (Thirlaway, Fallowfield, & Cuzick, 1996). Both, the FSFI-BC and the SAQ enquire about the reasons for lack of sexual activity. The FSFI-BC contains more questions that are specifically related to the areas of female sexual dysfunction – desire, arousal, orgasm, pain and distress. On the other hand, the SAQ's questions about the reasons for lack of activity are broader, covering partner variables, fatigue, physical limitations and lack of desire. Additionally, the SAQ has only been validated to date for use with women who are at risk of developing breast cancer and are receiving prophylactic hormone treatment (Thirlaway et al., 1996). Therefore, for the purposes of screening for sexual dysfunction in non-active women with breast cancer, the FSFI-BC may be more appropriate.

5.3 Implications of the Findings

5.3.1 Implications for theory

Psychometric properties (reliability and validity) are population specific (Streiner & Norman, 1995). Therefore if a measure has been developed and validated on one population (in the case of the FSFI, women with sexual functioning difficulties), it cannot be assumed that these properties hold for different samples of women (e.g., women diagnosed with breast cancer).

The present thesis provides an example of the necessity for the validation studies to be population specific. A number of studies have used the FSFI in the breast cancer context, assuming that the favourable psychometric properties empirically obtained on different populations would also hold true for the breast cancer population (Alder et al., 2008; Can et al., 2008; Ebrahimi et al., 2015; Farah et al., 2014; Harirchi et al., 2012; Pumo et al., 2012; Raggio et al., 2014; Sbitti et al., 2011; Schover et al., 2011; Speer et al., 2005).

Although most of the psychometric properties have been consistent across the various validation studies, some important differences emerged: (1) the FSFI in the breast cancer was better able to discriminate between women receiving and not receiving active treatment than the FSFI in gynaecological cancer contexts (Baser et al., 2012); (2) the confirmatory factor analysis of the FSFI did not provide evidence for calculation of the total score, which was contrary to findings in healthy women aged 18-25 (Opperman et al., 2013); and, (3) one of the items (item 14) of the FSFI does not work as well in the breast cancer context as it does in other populations (Baser et al., 2012; Forbes et al., 2014; Opperman et al., 2013; Rosen et al., 2000; Wiegel et al., 2005).

5.3.2 Implication for practitioners, service providers and policy makers

The FSFI and FSFI-BC have both shown adequate psychometric properties when administered to women diagnosed with breast cancer. Both measures are relatively short (the FSFI contains 19 and the FSFI-BC 34 items) and generally regarded as acceptable by the target audience of women the breast cancer. The FSFI-BC addresses the long-standing problems of the original FSFI, by including items specifically designed for women that are not sexually active as well as items measuring levels of distress, making it a useful scale for screening for sexual dysfunction in women with breast cancer. Based on the preliminary evidence obtained from the empirical Study 2, there is support to conclude that the FSFI-BC: (1) is a reliable and valid measure when administered to all women diagnosed with breast cancer, regardless of the frequency of sexual activity, and, (2) covers all areas of sexual dysfunction as well as distress, which is necessary for the diagnosis of sexual dysfunction (American Psychiatric Association, 2013; World Health Organization, 2004).

The FSFI-BC is a scale that is simple to administer, score and interpret, so various professionals can utilise it in their clinical practice, regardless of their familiarity with the underlying psychometric theory or sexual dysfunction generally. The Annon (1976) model for identification and treatment of sexual dysfunction, PLISSIT (P-Permission, LI-Limited Information, SS- Specific Suggestions, IT-Intensive Therapy) begins with a permission stage, where all professionals involved in supporting women with breast cancer should be able to provide a permission to talk about sexual difficulties (Dean, 2008; Pillai-Friedman & Ashline, 2014). Therefore, the FSFI-BC could be used by doctors, nurses, therapists, psychologists, social workers, occupational therapists and physiotherapists, to identify women who need additional support and provide the support according to the other levels of the PLISSIT model (if they feel they have the skills) or provide a referral to a more suited professional. Furthermore, the results of the FSFI-BC could be used as a 'conversation starter' to provide permission to talk about the sexual difficulties the women may experience. Lastly, there is emerging evidence from the genetic counselling field that using scales for the routine assessment of psychosocial problems may facilitate professionals' recognition and discussion of their clients' psychosocial problems, resulting in reduction of clients' distress (Eijzenga et al., 2014). Notwithstanding, good rapport, trust, sufficient time and a safe, comfortable and supportive environment are essential for free communication (Hodkinson, 2008) and would complement the use of the FSFI-BC in clinical practice with women diagnosed with breast cancer.

Due to the FSFI-BC being relatively short and well accepted by women with breast cancer, it is recommended that healthcare service providers and policy makers consider including it as a

routine measure that is administered intermittently throughout a woman's cancer journey. As it is a self-report measure, no additional staff time is required to administer the FSFI-BC, with only five minutes required to score and interpret the measure. Although this is unlikely to significantly increase the workload of health professionals, empirical data assessing the cost-effectiveness and burden to already-busy clinic staff should be obtained. In our research, the 10-15 minutes it took women to complete the FSFI-BC did not appear to be burdensome, highlighting its suitability for inclusion in general clinical care settings.

Given that changing routine clinical practice may be difficult in some contexts, the FSFI-BC could be promoted by outlining the likely burden routine administration would have on the health professionals and patients. Identifying health professionals who have a particular interest / passion for addressing sexual difficulties may be helpful in initial implementation of the FSFI-BC. These people could set-up local procedures for administration and scoring of the FSFI-BC and provide education to their colleagues. The data collected from the routine administration of the FSFI-BC (with appropriate ethical approvals and consents) could be used for research purposes, which may be another incentive for systematic implementation of this scale.

5.3.3 Implications for researchers

As discussed above, relatively little is known about women with breast cancer who are not sexually active, due to them being excluded from the studies using the FSFI (Alder et al., 2008; Can et al., 2008; Ebrahimi et al., 2015; Farah et al., 2014; Harirchi et al., 2012; Sbitti et al., 2011) or their scores being inappropriately interpreted (Pumo et al., 2012; Raggio et al., 2014; Schover et al., 2011; Speer et al., 2005). There is paucity of research about women who are not sexually active in the breast cancer literature, with only one study that could be located, which has specifically considered this group of women (Meyerowitz, Desmond, Rowland, Wyatt, & Ganz, 1999). Even in the seminal paper on predictors of sexual dysfunction in women with breast cancer, women who were not sexually active were excluded (Ganz et al., 1999). With questions specifically developed for women that have not been sexually active, researchers can use the FSFI-BC to explore the reasons for lack of sexual activity, thus obtaining more information about non-sexually active women.

Furthermore, with the inclusion of the items measuring distress experienced due to reported sexual difficulties, the FSFI-BC offers researchers a means to measure sexual dysfunction, as defined by diagnostic systems (American Psychiatric Association, 2013; World Health Organization, 2004). Previously, researchers needed to include a separate measure of distress (Frechette et al., 2013; Raggio et al., 2014) or have over-interpreted results of the FSFI to mean

the levels of sexual dysfunction (which implies significant levels of distress), rather than difficulties (Alder et al., 2008; Ebrahimi et al., 2015; Harirchi et al., 2012; Pumo et al., 2012; Sbitti et al., 2011; Schover et al., 2011; Speer et al., 2005).

5.4 Limitations

The results of the present thesis need to be considered in the view of the following limitations. First, both empirical studies used a convenience sample of women with breast cancer, who have indicated their willingness to contribute to research and have subsequently answered the invitation to participate in these studies. Therefore, it is unlikely that our samples included a representative sample of all women diagnosed with breast cancer currently living in Australia. Moreover, the online nature of these investigations may mean that our sample may be biased towards women who are familiar with using on-line technology.

Second, these studies were conducted only on Australian women. Although it is likely that these results apply to other English-speaking, Western countries, empirical evidence is needed to support this. It has previously been shown that the original FSFI is applicable and suitable for use across different cultures (Filocamo et al., 2014; Ryding & Blom, 2015; Takahashi, Inokuchi, Watanabe, Saito, & Kai, 2011; Wylomanski et al., 2014); however, obtaining data for cross cultural use of the FSFI-BC was beyond the scope of the present thesis.

Thirdly, both empirical studies contained a large sample of women with breast cancer (N=399 Study 1, N=596 Study 2), and the sub-sample of women who were not sexually active in the second study (N=166) was regarded as adequate according to sampling investigations conducted as a preliminary analysis (Fabrigar, Wegener, MacCallum, & Strahan, 1999). However, this sample size of non-active women was lower than the recommended 'rule of thumb' of 300 necessary to conduct validation studies, especially when using factor analysis (Rouquette & Falissard, 2011).

Lastly, the present thesis focused on sexual functioning of women with breast cancer. Males represent small but significant portion of people diagnosed with breast cancer and also report changes in sexual functioning following breast cancer diagnosis and treatment (Ruddy & Winer, 2013). There are significant differences between male and female sexual response (Basson, 2005), making the FSFI and FSFI-BC not suitable for use with males. Identifying appropriate scale measuring sexual dysfunction in males was beyond the scope of this thesis.

5.5 Future research

Future research should focus on further examining the psychometric properties of the FSFI-BC. It would be beneficial to replicate these results, using larger, more representative samples of women with breast cancer, especially those that are not sexually active. Researchers should empirically evaluate whether the FSFI-BC is appropriate for use in different cultural contexts, both English and non-English speaking. Concurrent validity could be demonstrated by comparing the FSFI-BC's performance against both diagnostic interviews and the original FSFI.

Confirmatory factor analysis of the FSFI-BC would provide evidence of the robustness of the factors extracted in the second empirical study. This is especially important as the literature is inconsistent about the delineation of desire and arousal subscales, with desire and arousal emerging as one factor when the exploratory factor analysis is utilised (Baser et al., 2012; Forbes et al., 2014; Rosen et al., 2000; Wiegel et al., 2005) and as separate factors following confirmatory factor analysis (Bartula & Sherman, 2015; Opperman et al., 2013).

Implementation of the FSFI-BC with larger samples of women with breast cancer would contribute to normative data, which would aid in the interpretation of scores. Score interpretation could also be aided by the development of clinical cut-off scores, by determining what scores could best delineate between women meeting diagnostic criteria for sexual dysfunction and those that do not. If the FSFI-BC were to be used to monitor effectiveness of sexual functioning treatments or breast cancer treatment side effects, the FSFI-BC's ability to detect clinically meaningful changes in functioning (sensitivity to change) also would need to be demonstrated.

The FSFI-BC was found to be acceptable to women with breast cancer that have completed this scale. What we understand about the acceptability of this measure would be further enhanced by obtaining empirical data from healthcare professionals who are likely to be administering the FSFI-BC (e.g., members of the medical or allied health teams). If the FSFI-BC is to be administered on a routine basis, the service providers and policy makers may value information about cost-effectiveness and perceived burden to the health professionals. Lastly, the development of an electronic version of the FSFI-BC that is accessible for both researchers and professionals may reduce the resources required for scoring and interpretation of this scale.

5.6 Conclusion

The aim of the present thesis was to identify a scale screening for sexual dysfunction that is simple, appropriate, reliable and valid, that could routinely be administered to the women with

breast cancer. Through conducting the thorough systematic review and two empirical studies, the FSFI-BC was developed and has provided evidence for excellent psychometric properties and acceptability to women with breast cancer. These preliminary data suggests that the FSFI-BC appears to be a valuable tool for screening for sexual dysfunction in both clinical practice and research.

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7.1 Appendix I: Female Sexual Function Index Adaptation for Breast Cancer Patients (FSFI-BC)

Female Sexual Function Index Adaptation for Breast Cancer Patients (FSFI-BC)

Many women experience changes in sexual functioning following diagnosis and treatment of breast cancer. Compared to my sexual functioning prior to breast cancer diagnosis and treatment:

	Decreased a lot	Decreased a little	Stayed the same	Increased a little	Increased a lot
1. My sexual desire	1	2	3	4	5
2. My arousal	1	2	3	4	5
3. My ability to get lubricated	1	2	3	4	5
4. My ability to reach orgasm	1	2	3	4	5
5. The satisfaction with my sex life	1	2	3	4	5

The following questions ask about your sexual feelings and responses during the past 4 weeks. In answering these questions the following definitions apply:

SEXUAL ACTIVITY can include caressing, foreplay, masturbation and vaginal intercourse

SEXUAL INTERCOURSE is defined as penile penetration (entry) of the vagina

SEXUAL STIMULATION includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

6. Over the past 4 weeks, how often did you feel sexual desire or interest?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

7. Over the past 4 weeks, how would you rate your level (degree) of sexual desire or interest?

Very high	High	Moderate	Low	Very low or none at all
5	4	3	2	1

8. Over the past 4 weeks, did you engage in sexual activity of any kind with a partner and / or by yourself (masturbation)?

No sexual activity of any kind with a partner and / or by myself (masturbation) ➔*Please complete SN1-15*
Sexual activity with a partner only ➔*Please complete SA1-15*
Sexual activity by yourself only ➔*Please complete SA1-15*
Sexual activity both with a partner and by yourself ➔*Please complete SA1-15*

Non-sexually active women only

Now think about any occasion over the last 4 weeks when sexual activity was a possibility but you did not have sexual activity.

Over the past 4 weeks, I did not have sexual activity or intercourse because:

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
SN1 I rarely felt aroused ('turned on')	5	4	3	2	1
SN2 I experienced a low level of arousal ('turn on')	5	4	3	2	1
SN3 I did not fee confident that I can become sexually aroused	5	4	3	2	1
SN4 I was not satisfied with my level of sexual arousal	5	4	3	2	1
SN5 I rarely got lubricated ('wet')	5	4	3	2	1
SN6 I find it hard to become lubricated ('wet')	5	4	3	2	1
SN7 I did not stay lubricated ('wet') until the end of sexual activity or intercourse	5	4	3	2	1
SN8 It was hard to stay lubricated ('wet') until the end of sexual activity or intercourse	5	4	3	2	1
SN9 I rarely achieve orgasm	5	4	3	2	1
SN10 I find it difficult to achieve orgasm	5	4	3	2	1
SN11 I was not satisfied with my ability to achieve orgasm	5	4	3	2	1
SN12 I feel pain or discomfort during sexual intercourse	5	4	3	2	1
SN13 I feel pain or discomfort after sexual intercourse	5	4	3	2	1
SN14 I feel intense and severe pain or discomfort during or after sexual intercourse	5	4	3	2	1
SN15 I was not satisfied with the amount of emotional closeness during sexual activity between me and my partner	5	4	3	2	1

➔ *Please skip SA1-15 questions and continue to 9.*

Sexually active women only

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

SA1 Over the past 4 weeks, how often did you feel sexually aroused ('turned on') during sexual activity or intercourse?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

SA2 Over the past 4 weeks, how would you rate your level of sexual arousal ('turn on') during sexual activity or intercourse?

Very high	High	Moderate	Low	Very low or none at all
5	4	3	2	1

SA3 Over the past 4 weeks, how confident were you about becoming sexually aroused during sexual activity or intercourse?

Very high confidence	High confidence	Moderate confidence	Low confidence	Very low or no confidence
5	4	3	2	1

SA4 Over the past 4 weeks, how often were you satisfied with your arousal ('turn on') during sexual activity or intercourse?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

SA5 Over the past 4 weeks, how often did you become lubricated ('wet') during sexual activity or intercourse?

Almost always or always	Not always but artificial lubricants were helpful in aiding my sexual activity or intercourse	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
6	5	4	3	2	1

SA6 Over the past 4 weeks, how difficult was it to become lubricated ('wet') during sexual activity or intercourse?

Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Difficult, but artificial lubricants were helpful in aiding my sexual activity or intercourse	Not difficult
1	2	3	4	5	6

SA7 Over the past 4 weeks, how often did you maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

Almost always or always	Not always but artificial lubricants were helpful in aiding my sexual activity or intercourse	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
6	5	4	3	2	1

SA8 Over the past 4 weeks, how <u>difficult</u> was it to maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Difficult, but artificial lubricants were helpful in aiding my sexual activity or intercourse	Not difficult
1	2	3	4	5	6

SA9 Over the past 4 weeks, when you had sexual stimulation or intercourse, how <u>often</u> did you reach orgasm?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

SA10 Over the past 4 weeks, when you had sexual stimulation or intercourse, how <u>difficult</u> was it for you to reach orgasm (climax)?

Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult
1	2	3	4	5

SA11 Over the past 4 weeks, how <u>satisfied</u> were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

SA12 Over the past 4 weeks, how <u>often</u> did you experience discomfort or pain during vaginal penetration?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
1	2	3	4	5

SA13 Over the past 4 weeks, how <u>often</u> did you experience discomfort or pain following vaginal penetration?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
1	2	3	4	5

SA14 Over the past 4 weeks, how would you rate your <u>level (degree)</u> of discomfort or pain during or following vaginal penetration?

Very high	High	Moderate	Low	Very low or none at all
1	2	3	4	5

SA15 Over the past 4 weeks, how <u>satisfied</u> have you been with the amount of emotional closeness during sexual activity between you and your partner?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

➔ *Please continue to 9 (below)*

Core questions – all women to answer

9. Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied	No partner
5	4	3	2	1	(Missing)

10. Over the past 4 weeks, how satisfied have you been with you overall sexual life?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

11. Over the past 4 weeks, how well were your sexual needs fulfilled?

Not at all	Slightly	Moderately	Very much	Extremely
1	2	3	4	5

12. Over the past 4 weeks, how would you rate your sex life?

Very poor	Poor	Neither good nor poor	Good	Very good
1	2	3	4	5

Over the past 4 weeks, how often did you feel distressed, bothered or frustrated about your...

	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
13. Sexual desire	1	2	3	4	5
14. Sexual arousal	1	2	3	4	5
15. Ability to orgasm	1	2	3	4	5
16. Ability to get lubricated ('wet')	1	2	3	4	5
17. Level of pain during sexual activity	1	2	3	4	5
18. Your sexual life	1	2	3	4	5

Supplementary partner questions

Over the past 4 weeks, my sexual functioning has been influenced by:

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
19. The availability of a partner	1	2	3	4	5
20. My partner's desire for sex	1	2	3	4	5
21. My partner's sexual problems	1	2	3	4	5
22. My partner's response to my body after the breast cancer or treatment	1	2	3	4	5

FSFI-BC Scoring

	Subscales	Items
Core – applicable to all women	Changes after cancer	C1+C2+C3+C4+C6
	Satisfaction	SN/SA15+C15+C16+C17 +C18
	Distress	C19+C20+C21+C22+C23+C24
Non-sexually active	Desire / Reason for inactivity – Arousal difficulties	C12+C13+SN1+SN2+SN3+SN4
	Reason for inactivity – Lubrication difficulties	SN5+SN6+SN7+SN8
	Reason for inactivity – Orgasm difficulties	SN9+SN10+SN11
	Reason for inactivity – Pain	SN12+SN13+SN14
Sexually active	Desire/Arousal	C12+C13+SA1+SA2+SA3+SA4
	Lubrication	SA5+SA6+SA7+SA8
	Orgasm	SA9+SA10+SA11
	Pain	SA12+SA13+SA14

FSFI-BC Clinical Interpretation Guidelines

Subscale	Individual items	Interpretation	Subscale scores	Interpretation
Changes after cancer	Scores 1 or 2	After cancer deterioration	<15 (individual item <3 x 5 items)	Sexual functioning deterioration after cancer; consider follow-up
Distress	Scores 1 or 2	Experiencing distress more than half the time	<18 (individual item scored <3 x 6 items)	Distress about sexual functioning experienced at least half the time; consider follow-up
Desire / reason for sexual inactivity	Scores 1 or 2	Difficulties in desire or arousal are contributing to sexual inactivity	<12 (individual item <3 x 4 items)	The difficulties in desire or arousal were contributing to sexual inactivity, consider follow-up
Reason for inactivity – lubrication	Scores 1 or 2	Lubrication difficulties are contributing to sexual inactivity	<12 (individual items <3 x 4 items)	Lubrication difficulties were contributing to sexual inactivity; consider follow-up
Reason for inactivity – orgasm	Scores 1 or 2	Difficulties reaching orgasm is contributing to sexual inactivity	<9 (individual items <3 x 3 items)	Difficulties reaching orgasm were contributing to sexual inactivity; consider follow-up
Reason for inactivity – pain	Scores 1 or 2	Pain is contributing to sexual inactivity	<9 (individual items <3 x 3 items)	Pain is contributing to sexual inactivity; consider follow-up

7.2 Appendix II: Conference presentation: 'Review of scales screening for sexual dysfunction in women diagnosed with breast cancer'

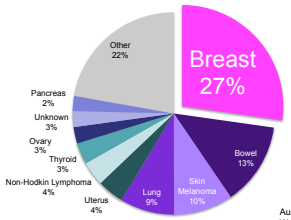
Presented at the Australasian Society for Behavioural Health and Medicine (ASBHM) 11th Annual Scientific Meeting in Auckland, 12th February 2014

Review of Scales Screening for Sexual Dysfunction in Women Diagnosed with Breast Cancer

Iris Bartula & A/Prof Kerry Sherman

Background

Breast cancer is the most commonly diagnosed cancer in females



Australian Institute of Health and Welfare & Australasian Association of Cancer Registries (2012)

Background

In women diagnosed with breast cancer, sexual dysfunction is:

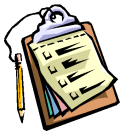
- Common
- Persistent
- With significant impact on women's quality of life

Why conduct this review?

- HOWEVER:
  - Less than 1/3 of patients reported ever discussing sexual difficulties with a health professional
    - Of these, few have reported being satisfied with the consultation

Why conduct this review?

- Possible solution: asking the patients to complete a quick self-report scale of sexual dysfunction
  - Identifying women with sexual dysfunction
  - 'Conversation starter'

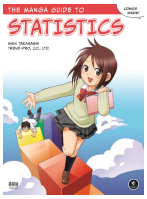


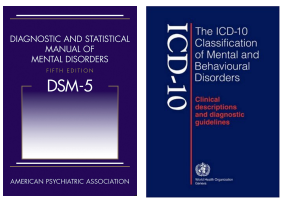
Why conduct this review?

- PROBLEM: numerous scales in literature

- SOLUTION: conducting this review

What did we look for in scales?





Psychometric properties of scales

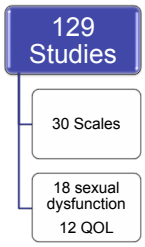
- Each scale had the following properties reviewed:
  - Reliability
  - Validity
  - Responsiveness to change
  - Acceptability to participants

DSM-5 / ICD-10 Dimensions of sexual dysfunction

- The following aspects of sexual dysfunction have been reviewed:
  - Desire
  - Arousal
  - Orgasm
  - Pain
  - Distress

How did we conduct this review?

Literature was searched from 1992-2013

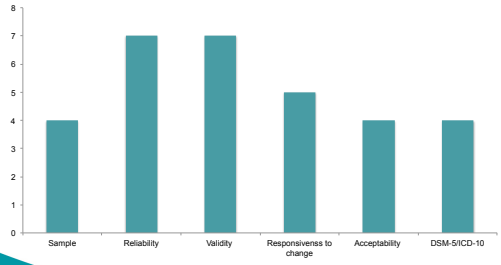


How did we conduct this review?

SCORING:

- Adequate psychometric properties
- Assessed the DSM-5 / ICD-10 aspects of sexual dysfunction
- Possible scores 0-17

General patterns that were noticed



…And the winners are:

Female Sexual Function Index (FSFI) (Rosen et al., 2000)
– Score 11

Sexual Problem Scale (SPS) (Perez et al., 2010)
– Score 10.5

Arizona Sexual Experience Scale (ASEX) (McGahuey et al., 2000)
– Score 10

Psychometric properties

	FSFI	SPS	ASEX
Breast cancer population	✗	✓	✗
Test – retest reliability	✓	✗	✓
Validity	✓	✓	✓

Conclusion: Once off measurement – SPS, repeated measurements FSFI, ASEX

DSM-5 / ICD-10 Criteria

	FSFI	SPS	ASEX
Desire	✓	✓	✓
Arousal	✓	✓	✓
Orgasm	✓	✓	✓
Pain	✓	✓	✗
Distress	✗	✗	✗

Conclusion: FSFI and SPS recommended as they cover more aspects.
Note: Distress needs to be measured separately

Practical issues

	FSFI	SPS	ASEX
Number of items	19	9	5
Electronic versions	✗	✗	✗
Ease of scoring	Moderate	Easy	Easy
Partner's variables	✗	✓	✗

Conclusion: SPS most practical

Future research

- Validation studies on breast cancer patients
- Include items measuring levels of distress
- Concurrent validities need to be demonstrated for most of the scales.

Thank you!

Further information on this review can be found in Breast Cancer Research and Treatment:

Bartula, I., & Sherman, K.A. (2013). Screening for sexual dysfunction in women diagnosed with breast cancer: systematic review and recommendations. *Breast Cancer Research and Treatment, 141*(2), 173-185. doi: 10.1007/s10549-013-2685-9

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7.3 Appendix III Conference Presentation: 'Female Sexual Function Index (FSFI): Is it suitable for use in breast cancer patients?'

Presented at the Australasian Society for Behavioural Health and Medicine (ASBHM) 11th Annual Scientific Meeting in Auckland, 12th February 2014

Female Sexual Function Index (FSFI): Is it suitable for use in breast cancer patients?

Iris Bartula & A/Prof Kerry Sherman

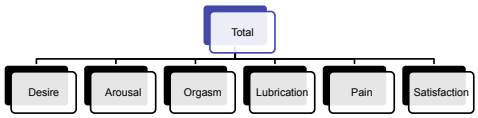
Background to the study

- Sexual dysfunction is common, persistent and not routinely addressed in clinical settings
- Self report screening tool would be useful
- BUT no gold standard exists

Female Sexual Function Index (FSFI)

(Rosen et al., 2000)

19 items



Female Sexual Function Index (FSFI)

- Promising psychometric properties
- Wide use in breast cancer research
- Not validated on breast cancer population

What did we investigate?

- Internal consistency
- Test-retest reliability
- Validity
- Acceptability

Participants

- Survey link sent to Breast Cancer Network Australia (BCNA) mailing list (approx 2000)
- Data collected over 2 time periods 2-4 weeks apart
- 25% excluded due to no recent sexual activity
- Final sample n=399^{T1},180^{T2}

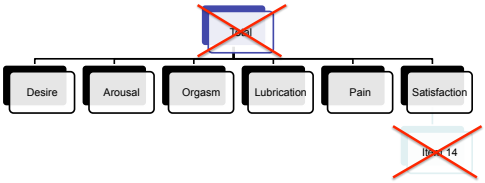
Measures

Construct	Measure
Sexual functioning	Cancer Rehabilitation Evaluation System (CARES) Sexual Functioning Subscale (Coscarelli & Heinrich, 1988) World Health Organization Quality of Life Assessment Instrument (WHOQOL-100) Sexual Activity Scale (The WHOQOL Group, 1998)
Body Image	Body Image Scale (BIS) (Hopwood, 1993)
Fatigue	Fatigue Assessment Scale (FAS) (Michielsen, De Vries, & Van Heck, 2003)
Mental Health	Impact of Events Scale (IES) (Horowitz, Wilner, & Alvarez, 1979) Depression, Anxiety and Stress Scale (DASS) (Lovibond & Lovibond, 1995) Medical Outcomes Study Health Survey (MOS SF-20) Mental Health Subscale (Stewart, Hays, & Ware, 1988)
Physical Health	Medical Outcomes Study Health Survey (MOS SF-20) Physical Health Subscale (Stewart, Hays, & Ware, 1988)
Relationship Adjustment	Revised Dyadic Adjustment Scale (RDAS) (Graham, Liu, & Jeziorski, 2006)

Results

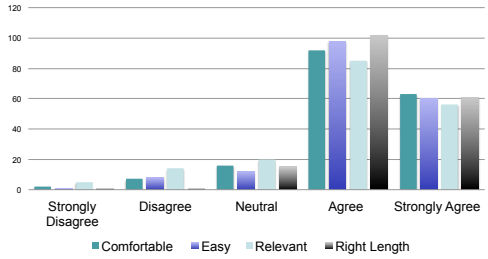
Property	Value	Interpretation
Internal Consistency	0.89 – 0.96	✓
Test-retest reliability	0.75 – 0.86	✓
Construct Validity	Small to moderate correlations	✓
Concurrent Validity	Moderate to high correlations	✓

What does FSFI structure look like?



(TLI=0.95, CFI=0.97, RMSEA=0.07)

Acceptability



Take home message:

FSFI has now been validated on breast cancer patients it is suitable for use

Recommendations

- Interpret FSFI only if participants had sexual activity in the past 4 weeks
- Calculate subscales only, total score is not valid
- Omit item 14
- Additional information about the level of distress is necessary

Suggested uses of the FSFI

- FSFI that does not require any additional training to administer, score and interpret.
- We recommend that the FSFI is used as routine screener by:
  - Medical practitioners
  - Nurses
  - Psychologists, counsellors, sex therapists
  - Social workers
  - Occupational Therapists
  - Researchers

Future research

- Adapt FSFI questions to make them suitable for women not experiencing recent sexual activity
- Add items assessing levels of distress necessary for diagnosis
- Assess partner contribution to reported sexual dysfunction

Thank you!

7.4 Appendix IV– Ethics Approval Letter for the 'The Female Sexual Function Index (FSFI): evaluation of acceptability, reliability, and validity in women with breast cancer' (Empirical Study 1)

MACQUARIE UNIVERSITY

IRIS BARTULA <iris.kemp@students.mq.edu.au>

Approved- Ethics application- Sherman (Ref No: 5201200487)

1 message

Ethics Secretariat <ethics.secretariat@mq.edu.au> Thu, Sep 13, 2012 at 11:46 AM
To: Dr Kerry Sherman <kerry.sherman@mq.edu.au>
Cc: Ms Iris Bartula <iris.bartula@students.mq.edu.au>

Dear Dr Sherman

Re: "Validation of the Female Sexual Functioning Index among women diagnosed with Breast Cancer" (Ethics Ref: 5201200487)

Thank you for your recent correspondence. Your response has addressed the issues raised by the Human Research Ethics Committee and you may now commence your research.

This research meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). The National Statement is available at the following web site:

http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf.

The following personnel are authorised to conduct this research:

Dr Kerry Sherman
Ms Iris Bartula

NB. STUDENTS: IT IS YOUR RESPONSIBILITY TO KEEP A COPY OF THIS APPROVAL EMAIL TO SUBMIT WITH YOUR THESIS.

Please note the following standard requirements of approval:

1. The approval of this project is conditional upon your continuing compliance with the National Statement on Ethical Conduct in Human Research (2007).

2. Approval will be for a period of five (5) years subject to the provision of annual reports.

Progress Report 1 Due: 13 September 2013
Progress Report 2 Due: 13 September 2014
Progress Report 3 Due: 13 September 2015
Progress Report 4 Due: 13 September 2016
Final Report Due: 13 September 2017

NB. If you complete the work earlier than you had planned you must submit a Final Report as soon as the work is completed. If the project has been discontinued or not commenced for any reason, you are also required to submit a Final Report for the project.

Progress reports and Final Reports are available at the following website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/forms

3. If the project has run for more than five (5) years you cannot renew approval for the project. You will need to complete and submit a Final Report and submit a new application for the project. (The five year limit on renewal of approvals allows the Committee to fully re-review research in an environment where legislation, guidelines and requirements are continually changing, for example, new child protection and privacy laws).

4. All amendments to the project must be reviewed and approved by the Committee before implementation. Please complete and submit a Request for Amendment Form available at the following website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/forms

5. Please notify the Committee immediately in the event of any adverse effects on participants or of any unforeseen events that affect the continued ethical acceptability of the project.

6. At all times you are responsible for the ethical conduct of your research in accordance with the guidelines established by the University. This information is available at the following websites:

http://www.mq.edu.au/policy/

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/policy

If you will be applying for or have applied for internal or external funding for the above project it is your responsibility to provide the Macquarie University's Research Grants Management Assistant with a copy of this email as soon as possible. Internal and External funding agencies will not be informed that you have final approval for your project and funds will not be released until the Research Grants Management Assistant has received a copy of this email.

Please retain a copy of this email as this is your official notification of final ethics approval.

Yours sincerely
Dr Karolyn White
Director of Research Ethics
Chair, Human Research Ethics Committee

7.5 Appendix V – Measures used in the 'The Female Sexual Function Index (FSFI): evaluation of acceptability, reliability, and validity in women with breast cancer' (Empirical Study 1)

7.5.1 Time 1 Survey

7.5.1.1 Demographic Information

How did you find about this survey?

Breast Cancer Network Australia (BCNA)	Breast Cancer Care Western Australia	Gumtree	Other (Please Specify)
1	2	3	4

Please indicate where you were born?

Australia	New Zealand	Pacific Islands	UK / Ireland	Western Europe	Eastern Europe	Middle East	Asia	Other
1	2	3	4	5	6	7	8	9

What is your relationship status?

Partnered	Single
1	2

How long have you been in relationship for (in years)?

How many children do you have?

What is your age?

What is the highest level you education you have completed?

Less than Year 10	School Certificate	High School Certificate	Vocational / TAFE	Some university	Bachelor's degree	Postgraduate degree
1	2	3	4	5	6	7

What is your employment status?

Employed full time	Employed part-time	Employed as a casual	Unemployed / looking for work	Retired
1	2	3	4	5

What is your approximate household income?

$0-$50,000	$50,000-$100,000	$100,000-$150,000	$150,000-$200,000	$200,000+	I prefer not to answer
1	2	3	4	5	Missing

What is your current menopausal status?

Premenopausal	Postmenopausal (no periods for at least 6 months)
1	2

What was your menopausal status before diagnosis of breast cancer / DCIS?

Premenopausal	Postmenopausal (no periods for at least 6 months)
1	2

What is your current diagnosis?

DCIS	Early stage breast Cancer	Metastatic breast cancer
1	2	3

What is the month/year of diagnosis?

What type of surgery did you have for the treatment of breast cancer / DCIS?

Lumpectomy / wide local excision	Single mastectomy	Double mastectomy	Mastectomy with reconstruction
1	2	3	4

What type of reconstruction did you have?

Implant	Flap
1	2

What type of flap did you have?

TRAM Flap	DIEP Flap	Latisimus Dorsi Muscle Flap
1	2	3

What other treatment have you had?

None	Chemotherapy	Radiation therapy	Hormonal therapy
1	2	3	4

What treatment are you currently receiving?

None	Chemotherapy	Radiation therapy	Hormonal therapy
1	2	3	4

7.5.1.2 Fatigue Assessment Scale (FAS)

The following 10 statements refer to how you USUALLY feel

	Never	Sometimes	Regularly	Often	Always
I am bothered by fatigue	1	2	3	4	5
I get tired very quickly	1	2	3	4	5
I don't do much during the day	1	2	3	4	5
I have enough energy for everyday life*	1	2	3	4	5
Physically, I feel exhausted	1	2	3	4	5
I have problems starting things	1	2	3	4	5
I have problems thinking clearly	1	2	3	4	5
I feel no desire to do anything	1	2	3	4	5
Mentally, I feel exhausted	1	2	3	4	5
When I am doing something, I can concentrate quite well*	1	2	3	4	5

* Reverse-scored

7.5.1.3 Revised Dyadic Adjustment Scale (RDAS)

Most people have disagreements in their relationships. Please indicate below the approximate extent of agreement or disagreement between you and your partner for each item on the following list.

	Always agree	Almost always agree	Occasionally agree	Frequently disagree	Almost always disagree
Religious matters*	1	2	3	4	5
Demonstrations of affection*	1	2	3	4	5
Making major decisions*	1	2	3	4	5
Sex relations*	1	2	3	4	5
Conventionality (correct and proper behaviour)*	1	2	3	4	5
Career decisions*	1	2	3	4	5

How often…

	All the time	Most of the time	More often than not	Occasionally	Rarely	Never
Have you discussed or have you considered divorce, separation or terminating your relationship?	1	2	3	4	5	6
Do you and your partner quarrel?	1	2	3	4	5	6
Do you regret that you married (or lived together)?	1	2	3	4	5	6
Do you and your mate 'get on each other's nerves'?	1	2	3	4	5	6

How often…

	Every day	Almost every day	Occasionally	Rarely	Never
Do you and your mate engage in outside interests together?*	1	2	3	4	5

How often would you say the following events occur between you and your mate?

	Never	Less than once a month	Once or twice a month	Once or twice a week	Once a day
Having a stimulating exchange of ideas	1	2	3	4	5
Working together on a project	1	2	3	4	5
Calmly discussing something	1	2	3	4	5

* Reverse scored

7.5.1.4 Depression, Anxiety and Stress Scale Short Form (DASS-21)

Please read each statement and indicate how much the statement applied to you OVER THE PAST WEEK. There are no right or wrong answers. Do not spend too much time on any statement.

	Did not apply to me at all	Applied to me to some degree OR some of the time	Applied to me to a considerable degree OR a good part of the time	Applied to me very much OR most of the time
I found it hard to wind down	1	2	3	4
I was aware of dryness in my mouth	1	2	3	4
I couldn't seem to experience any positive feelings at all	1	2	3	4
I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	1	2	3	4
I found it difficult to work up initiative to do things	1	2	3	4
I tended to over-react to situations	1	2	3	4
I experienced trembling (e.g. in the hands)	1	2	3	4
I felt like I was using a lot of nervous energy	1	2	3	4
I was worried about situations in which I may panic and make a fool of myself	1	2	3	4
I felt I had nothing to look forward to	1	2	3	4
I found myself getting agitated	1	2	3	4
I found it difficult to relax	1	2	3	4
I felt down-hearted and blues	1	2	3	4
I was intolerant of anything that kept me from getting on with what I was doing	1	2	3	4
I felt close to panic	1	2	3	4
I was unable to become enthusiastic about anything	1	2	3	4
I felt I was not worth much as a person	1	2	3	4
I felt I was rather touchy	1	2	3	4
I was aware of the action of my heart in the absence of physical exertion (e.g. sense of hear rate increase, heart missing a beat)	1	2	3	4
I felt scared without any good reason	1	2	3	4
I felt that life was meaningless	1	2	3	4

7.5.1.5 Body Image Scale (BIS)

In this questionnaire you will be asked about how you feel about your appearance, and about any changes that may have resulted from your disease or treatment. Please indicate how you have been feeling DURING THE PAST WEEK.

	Not at all	A little	Quite a bit	Very much
Have you been feeling self-conscious about your appearance?	1	2	3	4
Have you felt less physically attractive as a result of your disease or treatment?	1	2	3	4
Have you been dissatisfied with your appearance when dressed?	1	2	3	4
Have you been feeling less feminine as a result of your disease or treatment?	1	2	3	4
Did you find it difficult to look at yourself naked?	1	2	3	4
Have you been feeling less sexually attractive as a result of your disease or treatment?	1	2	3	4
Did you avoid people because of the way you felt about your appearance?	1	2	3	4
Have you been feeling the treatment left your body as less whole?	1	2	3	4
Have you felt dissatisfied with your body?	1	2	3	4
Have you been dissatisfied with the appearance of your scar?	1	2	3	4

7.5.1.6 Impact of events scale (IES)

Breast cancer diagnosis and treatment are stressful for many women. Below is a list of comments made by people after stressful life events. Please indicate how frequently these comments were true about the breast cancer diagnosis and treatment DURING THE PAST WEEK. If they did not occur during this time, please mark the "not at all" column.

	Not at all	Rarely	Sometimes	Often
I thought about it when I did not mean to	1	2	3	4
I avoided letting myself get upset when I thought about it or was reminded of it	1	2	3	4
I tried to remove it from my memory	1	2	3	4
I had trouble falling asleep, because of pictures or thoughts about it that came into my mind	1	2	3	4
I had waves of strong feelings about it	1	2	3	4
I had dreams about it	1	2	3	4
I stayed away from reminders of it	1	2	3	4
I felt as if it hadn't happened or it was not real	1	2	3	4
I tried not to talk about it	1	2	3	4
Pictures about it popped into my mind	1	2	3	4
Other things kept making me think about it	1	2	3	4
I was aware that I still had a lot of feelings about it, but I didn't deal with them	1	2	3	4
I tried not think about it	1	2	3	4
Any reminder brought back the feelings about it	1	2	3	4
My feelings about it were kind of numb	1	2	3	4

7.5.1.7 Medical Outcomes study, Short Form (MOS-20)

In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
5	4	3	2	1

How much bodily pain have you had during past 4 weeks?

None	Very mild	Mild	Moderate	Severe
5	4	3	2	1

How long (if at all) has your health limited you in each of the following activities?

	Limited for more than 3 months	Limited for 3 months or less	Not limited at all
The kinds or amounts of vigorous activities you can do, like lifting heavy objects, running or participating in strenuous sports	1	2	3
The kinds or amounts of moderate activities you can do, like moving a table, carrying groceries or bowling	1	2	3
Walking uphill or climbing a few flights of stairs	1	2	3
Bending, lifting, or stooping	1	2	3
Walking one block	1	2	3
Eating, dressing, bathing, or using the toilet	1	2	3

Does your health keep you from working at a job, doing workaround the house or going to school?

Yes, for more than 3 months	Yes, for 3 months or less	No
1	2	3

Have you been unable to do certain kinds of housework or schoolwork because of your health?

Yes, for more than 3 months	Yes, for 3 months or less	No
1	2	3

For the each of the following questions, please check the box for the one answer that comes closest to the way you have been feeling DURING THE PAST MONTH

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
How much time, has your health limited your social activities (like visiting friends or close relatives)?	1	2	3	4	5	6
How much time have you been a nervous person?	1	2	3	4	5	6
How much time have you felt calm and peaceful?*	1	2	3	4	5	6
How much time have you felt downhearted and blue?	1	2	3	4	5	6

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
How much time have you been a happy person?*	1	2	3	4	5	6
How often have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6

Please check the box that best describes whether each of the following statements is true or false for you

	Definitely true	Mostly true	Not true	Mostly false	Definitely false
I am somewhat ill	1	2	3	4	5
I am as healthy as anybody I know*	1	2	3	4	5
My health is excellent*	1	2	3	4	5
I have been feeling bad lately	1	2	3	4	5

* Reverse scored

7.5.1.8 Cancer Rehabilitation Evaluation System (CARES) Sexual Functioning Subscale

Below is a list of problem statements that describe situations and experiences of individuals who have had cancer. Read each statement and circle the number that describes how much each statement applies to you DURING THE LAST FOUR WEEKS

	Not at all	A little	A fair amount	Much	Very much
I do not feel sexually attractive	1	2	3	4	5
I do not feel my partner finds me sexually attractive	1	2	3	4	5
I am not interested in having sex	1	2	3	4	5
I do not think my partner is interested in having sex	1	2	3	4	5

Have you been sexually active since cancer diagnosis?

Yes	No
1	2

Since cancer diagnosis…

	Not at all	A little	A fair amount	Much	Very much
I find the frequency of sexual activity has decreased	1	2	3	4	5
I have difficulty becoming sexually aroused	1	2	3	4	5
I have difficulty getting lubricated	1	2	3	4	5
I have difficulty reaching orgasm	1	2	3	4	5

7.5.1.9 Female Sexual Function Index (FSFI)

The following questions ask about your sexual feelings and responses during the past 4 weeks. In answering these questions the following definitions apply:

SEXUAL ACTIVITY can include caressing, foreplay, masturbation and vaginal intercourse
SEXUAL INTERCOURSE is defined as penile penetration (entry) of the vagina
SEXUAL STIMULATION includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

Over the past 4 weeks, how often did you feel sexual desire or interest?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

Over the past 4 weeks, how would you rate your level (degree) of sexual desire or interest?

Very high	High	Moderate	Low	Very low
5	4	3	2	1

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions

Over the past 4 weeks, how often did you feel sexually aroused ('turned on') during sexual activity or intercourse?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, how would you rate your level of sexual arousal ('turn on') during sexual activity or intercourse?

No sexual activity	Very high	High	Moderate	Low	Very low or none at all
0	5	4	3	2	1

Over the past 4 weeks, how confident were you about becoming sexually aroused during sexual activity or intercourse?

No sexual activity	Very high confidence	High confidence	Moderate confidence	Low confidence	Very low or no confidence
0	5	4	3	2	1

Over the past 4 weeks, how often were you satisfied with your arousal ('turn on') during sexual activity or intercourse?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, how often did you become lubricated ('wet') during sexual activity or intercourse?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, how difficult was it to become lubricated ('wet') during sexual activity or intercourse?

No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult
0	5	4	3	2	1

Over the past 4 weeks, how often did you maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, how difficult was it to maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult
0	5	4	3	2	1

Over the past 4 weeks, when you had sexual stimulation or intercourse, how often did you reach orgasm?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, when you had sexual stimulation or intercourse, how difficult was it for you to reach orgasm (climax)?

No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult
0	5	4	3	2	1

Over the past 4 weeks, how satisfied were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
0	5	4	3	2	1

Over the past 4 weeks, how often did you experience discomfort or pain during vaginal penetration?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	1	2	3	4	5

Over the past 4 weeks, how often did you experience discomfort or pain following vaginal penetration?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	1	2	3	4	5

Over the past 4 weeks, how would you rate your level (degree) of discomfort or pain during or following vaginal penetration?

No sexual activity	Very high	High	Moderate	Low	Very low or none at all
0	5	4	3	2	1

Over the past 4 weeks, how satisfied have you been with the amount of emotional closeness during sexual activity between you and your partner?

No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
0	5	4	3	2	1

Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

Over the past 4 weeks, how satisfied have you been with you overall sexual life?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

7.5.1.10 The World Health Organization Quality of Life Assessment Instrument (WHOQOL-100)

The following questions ask you how much you have experienced certain things in the LAST 4 WEEKS.

	Not at all	Slightly	Moderately	Very much	Extremely
How well were your sexual needs fulfilled?	1	2	3	4	5
Are you bothered by any difficulties in your sex life	1	2	3	4	5

In the LAST 4 WEEKS…

	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
How satisfied were you with your sex life?	1	2	3	4	5

In the LAST 4 WEEKS…

	Very poor	Poor	Neither poor nor good	Good	Very good
How would you rate your sex life?	1	2	3	4	5

7.5.2 Time 2 Survey

7.5.2.1 Female Sexual Function Index (FSFI)

The following questions ask about your sexual feelings and responses during the past 4 weeks. In answering these questions the following definitions apply:

SEXUAL ACTIVITY can include caressing, foreplay, masturbation and vaginal intercourse
SEXUAL INTERCOURSE is defined as penile penetration (entry) of the vagina
SEXUAL STIMULATION includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

Over the past 4 weeks, how often did you feel sexual desire or interest?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

Over the past 4 weeks, how would you rate your level (degree) of sexual desire or interest?

Very high	High	Moderate	Low	Very low
5	4	3	2	1

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions

Over the past 4 weeks, how often did you feel sexually aroused ('turned on') during sexual activity or intercourse?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, how would you rate your level of sexual arousal ('turn on') during sexual activity or intercourse?

No sexual activity	Very high	High	Moderate	Low	Very low or none at all
0	5	4	3	2	1

Over the past 4 weeks, how confident were you about becoming sexually aroused during sexual activity or intercourse?

No sexual activity	Very high confidence	High confidence	Moderate confidence	Low confidence	Very low or no confidence
0	5	4	3	2	1

Over the past 4 weeks, how often were you satisfied with your arousal ('turn on') during sexual activity or intercourse?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, how often did you become lubricated ('wet') during sexual activity or intercourse?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, how difficult was it to become lubricated ('wet') during sexual activity or intercourse?

No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult
0	5	4	3	2	1

Over the past 4 weeks, how often did you maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, how difficult was it to maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult
0	5	4	3	2	1

Over the past 4 weeks, when you had sexual stimulation or intercourse, how often did you reach orgasm?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	5	4	3	2	1

Over the past 4 weeks, when you had sexual stimulation or intercourse, how difficult was it for you to reach orgasm (climax)?

No sexual activity	Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult
0	5	4	3	2	1

Over the past 4 weeks, how satisfied were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
0	5	4	3	2	1

Over the past 4 weeks, how often did you experience discomfort or pain during vaginal penetration?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	1	2	3	4	5

Over the past 4 weeks, how often did you experience discomfort or pain following vaginal penetration?

No sexual activity	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
0	1	2	3	4	5

Over the past 4 weeks, how would you rate your level (degree) of discomfort or pain during or following vaginal penetration?

No sexual activity	Very high	High	Moderate	Low	Very low or none at all
0	5	4	3	2	1

Over the past 4 weeks, how satisfied have you been with the amount of emotional closeness during sexual activity between you and your partner?

No sexual activity	Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
0	5	4	3	2	1

Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

Over the past 4 weeks, how satisfied have you been with you overall sexual life?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

7.5.2.2 Acceptability questions

Please rate the following statements about the questions that you answered so far today. All questions belong to a single questionnaire

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I felt comfortable answering the questions	1	2	3	4	5
The questions were easy to complete	1	2	3	4	5
The questions were relevant to my experiences	1	2	3	4	5
The questionnaire above was about the right length	1	2	3	4	5

In the space below, please provide any other feedback about the questionnaire above (e.g. what worked well, how it can be improved)

7.6 Appendix VI – Ethics approval letter for the 'Development and initial validation of the Female Sexual Function Index adaptation for breast cancer patients (FSFI-BC)' (Empirical Study 2)

Office of the Deputy Vice-Chancellor (Research)

Research Office
C5C Research HUB East, Level 3, Room 324
MACQUARIE UNIVERSITY NSW 2109 AUSTRALIA

Phone **+61 (0)2 9850 4194**
Fax +61 (0)2 9850 4465
Email ethics.secretariat@mq.edu.au

26 June 2014

A/Prof Kerry Sherman
Department of Psychology
Faculty of Human Sciences
Macquarie University NSW 2109

Dear Associate Professor Sherman

RE: *Creation and initial validation of the Female Sexual Functioning Index for women diagnosed with breast cancer (FSFI-BC)*

Thank you for submitting the above application for ethical and scientific review. Your application was considered by the Macquarie University Human Research Ethics Committee (HREC (Medical Sciences)) at its meeting on 29/05/2014 at which further information was requested to be reviewed by the Ethics Secretariat.

The requested information was received with correspondence on 19/6/2014.

I am pleased to advise that ethical and scientific approval has been granted for this project to be conducted at:

- Macquarie University

This research meets the requirements set out in the *National Statement on Ethical Conduct in Human Research* (2007 – Updated March 2014) (the *National Statement*).

Details of this approval are as follows:

Reference No: 5201400594

Approval Date: 26/06/2014

The following documentation has been reviewed and approved by the HREC (Medical Sciences):

Documents reviewed	Version no.	Date
Macquarie University Ethics Application Form	2.3	July 2013
Correspondence from Iris Bartula responding to the issues raised by the HREC (Medical Sciences)		Received 19/6/2014
Advertisement entitled *Intimacy and Sexuality in Women Diagnosed with Breast Cancer Study*	1	21/5/2014
MQ Participant Information and Consent Form (PICF) entitled *Intimacy and Sexuality in Women Diagnosed with Breast Cancer Study (Part II)*	1	21/05/2014
BCNA Review & Survey Group Request Form	1	21/05/2014
FSBI-BC Survey Time 1	1	20/5/2014

This letter constitutes ethical and scientific approval only.

Standard Conditions of Approval:

1. Continuing compliance with the requirements of the *National Statement,* which is available at the following website:

http://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research

2. This approval is valid for five (5) years, subject to the submission of annual reports. Please submit your reports on the anniversary of the approval for this protocol.

3. All adverse events, including events which might affect the continued ethical and scientific acceptability of the project, must be reported to the HREC within 72 hours.

4. Proposed changes to the protocol must be submitted to the Committee for approval before implementation.

It is the responsibility of the Chief investigator to retain a copy of all documentation related to this project and to forward a copy of this approval letter to all personnel listed on the project.

Should you have any queries regarding your project, please contact the Ethics Secretariat on 9850 4194 or by email ethics.secretariat@mq.edu.au

The HREC (Medical Sciences) Terms of Reference and Standard Operating Procedures are available from the Research Office website at:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics

The HREC (Medical Sciences) wishes you every success in your research.

Yours sincerely

Professor Tony Eyers
Chair, Macquarie University Human Research Ethics Committee (Medical Sciences)

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

7.7 Appendix VII – Measures used in the 'Development and initial validation of the Female Sexual Function Index adaptation for breast cancer patients (FSFI-BC)' (Empirical Study 2)

7.7.1 Time 1 Survey

7.7.1.1 Demographic Information

How did you find about this survey?

Breast Cancer Network Australia (BCNA)	Breast Cancer Care Western Australia	Register4	Other (Please Specify)
1	2	3	4

What is your age (in years)?

What is your relationship status?

Partnered (e.g. married, de-facto, in a relationship)	Single
1	2

How long have you been in relationship for (in years)?

How many children do you have?

Please indicate where you were born?

Australia	New Zealand	Pacific Islands	UK / Ireland	Western Europe	Eastern Europe	Middle East	Asia	Other
1	2	3	4	5	6	7	8	9

What is the highest level you education you have completed?

Less than Year 10	School Certificate	High School Certificate	Vocational / TAFE	Some university	Bachelor's degree	Postgraduate degree
1	2	3	4	5	6	7

What is your employment status?

Employed full time	Employed part-time	Employed as a casual	Unemployed / looking for work	Retired
1	2	3	4	5

What is your current menopausal status?

Premenopausal	Postmenopausal (no periods for at least 6 months)
1	2

What is your current diagnosis?

DCIS	Early stage breast Cancer	Metastatic breast cancer
1	2	3

What was the month/year of diagnosis?

What type of surgery did you have for the treatment of breast cancer / DCIS?

Lumpectomy / wide local excision	Single mastectomy	Double mastectomy	Mastectomy with reconstruction
1	2	3	4

What type of reconstruction did you have?

Implant	Flap
1	2

What type of flap did you have?

TRAM Flap	DIEP Flap	Latisimus Dorsi Muscle Flap
1	2	3

What other treatment have you had?

None	Chemotherapy	Radiation therapy	Hormonal therapy
1	2	3	4

What type of treatment do you currently receive?

None	Chemotherapy	Radiation therapy	Hormonal therapy
1	2	3	4

7.7.1.2 Fatigue Assessment Scale (FAS)

The following 10 statements refer to how you USUALLY feel

	Never	Sometimes	Regularly	Often	Always
I am bothered by fatigue	1	2	3	4	5
I get tired very quickly	1	2	3	4	5
I don't do much during the day	1	2	3	4	5
I have enough energy for everyday life*	1	2	3	4	5
Physically, I feel exhausted	1	2	3	4	5
I have problems starting things	1	2	3	4	5
I have problems thinking clearly	1	2	3	4	5
I feel no desire to do anything	1	2	3	4	5
Mentally, I feel exhausted	1	2	3	4	5
When I am doing something, I can concentrate quite well*	1	2	3	4	5

* Reverse-scored

7.7.1.3 Body Image Scale (BIS)

In this questionnaire you will be asked about how you feel about your appearance, and about any changes that may have resulted from your disease or treatment. Please indicate how you have been feeling DURING THE PAST WEEK.

	Not at all	A little	Quite a bit	Very much
Have you been feeling self-conscious about your appearance?	1	2	3	4
Have you felt less physically attractive as a result of your disease or treatment?	1	2	3	4
Have you been dissatisfied with your appearance when dressed?	1	2	3	4
Have you been feeling less feminine as a result of your disease or treatment?	1	2	3	4
Did you find it difficult to look at yourself naked?	1	2	3	4
Have you been feeling less sexually attractive as a result of your disease or treatment?	1	2	3	4
Did you avoid people because of the way you felt about your appearance?	1	2	3	4
Have you been feeling the treatment left your body as less whole?	1	2	3	4
Have you felt dissatisfied with your body?	1	2	3	4
Have you been dissatisfied with the appearance of your scar?	1	2	3	4

7.7.1.4 Medical Outcomes study, Short Form (MOS-20)

In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
5	4	3	2	1

How much bodily pain have you had during past 4 weeks?

None	Very mild	Mild	Moderate	Severe
5	4	3	2	1

How long (if at all) has your health limited you in each of the following activities?

	Limited for more than 3 months	Limited for 3 months or less	Not limited at all
The kinds or amounts of vigorous activities you can do, like lifting heavy objects, running or participating in strenuous sports	1	2	3
The kinds or amounts of moderate activities you can do, like moving a table, carrying groceries or bowling	1	2	3
Walking uphill or climbing a few flights of stairs	1	2	3
Bending, lifting, or stooping	1	2	3
Walking one block	1	2	3
Eating, dressing, bathing, or using the toilet	1	2	3

Does your health keep you from working at a job, doing workaround the house or going to school?

Yes, for more than 3 months	Yes, for 3 months or less	No
1	2	3

Have you been unable to do certain kinds of housework or schoolwork because of your health?

Yes, for more than 3 months	Yes, for 3 months or less	No
1	2	3

For the each of the following questions, please check the box for the one answer that comes closest to the way you have been feeling DURING THE PAST MONTH

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
How much time, has your health limited your social activities (like visiting friends or close relatives)?	1	2	3	4	5	6
How much time have you been a nervous person?	1	2	3	4	5	6
How much time have you felt calm and peaceful?*	1	2	3	4	5	6
How much time have you felt downhearted and blue?	1	2	3	4	5	6

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
How much time have you been a happy person?*	1	2	3	4	5	6
How often have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6

Please check the box that best describes whether each of the following statements is true or false for you

	Definitely true	Mostly true	Not true	Mostly false	Definitely false
I am somewhat ill	1	2	3	4	5
I am as healthy as anybody I know*	1	2	3	4	5
My health is excellent*	1	2	3	4	5
I have been feeling bad lately	1	2	3	4	5

* Reverse scored

7.7.1.5 Revised Dyadic Adjustment Scale (RDAS)

Most people have disagreements in their relationships. Please indicate below the approximate extent of agreement or disagreement between you and your partner for each item on the following list.

	Always agree	Almost always agree	Occasionally agree	Frequently disagree	Almost always disagree
Religious matters*	1	2	3	4	5
Demonstrations of affection*	1	2	3	4	5
Making major decisions*	1	2	3	4	5
Sex relations*	1	2	3	4	5
Conventionality (correct and proper behaviour)*	1	2	3	4	5
Career decisions*	1	2	3	4	5

How often…

	All the time	Most of the time	More often than not	Occasionally	Rarely	Never
Have you discussed or have you considered divorce, separation or terminating your relationship?	1	2	3	4	5	6
Do you and your partner quarrel?	1	2	3	4	5	6
Do you regret that you married (or lived together)?	1	2	3	4	5	6
Do you and your mate 'get on each other's nerves'?	1	2	3	4	5	6

How often…

	Every day	Almost every day	Occasionally	Rarely	Never
Do you and your mate engage in outside interests together?*	1	2	3	4	5

How often would you say the following events occur between you and your mate?

	Never	Less than once a month	Once or twice a month	Once or twice a week	Once a day
Having a stimulating exchange of ideas	1	2	3	4	5
Working together on a project	1	2	3	4	5
Calmly discussing something	1	2	3	4	5

* Reverse scored

7.7.1.6 Female Sexual Function Index, Breast Cancer Adaptation (FSFI-BC)

Many women experience changes in sexual functioning following diagnosis and treatment of breast cancer. Compared to my sexual functioning prior to breast cancer diagnosis and treatment:

	Decreased a lot	Decreased a little	Stayed the same	Increased a little	Increased a lot
1. My sexual desire	1	2	3	4	5
2. My arousal	1	2	3	4	5
3. My ability to get lubricated	1	2	3	4	5
4. My ability to reach orgasm	1	2	3	4	5
5. The satisfaction with my sex life	1	2	3	4	5

The following questions ask about your sexual feelings and responses during the past 4 weeks. In answering these questions the following definitions apply:

SEXUAL ACTIVITY can include caressing, foreplay, masturbation and vaginal intercourse

SEXUAL INTERCOURSE is defined as penile penetration (entry) of the vagina

SEXUAL STIMULATION includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

6. Over the past 4 weeks, how often did you feel sexual desire or interest?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

7. Over the past 4 weeks, how would you rate your level (degree) of sexual desire or interest?

Very high	High	Moderate	Low	Very low or none at all
5	4	3	2	1

8. Over the past 4 weeks, did you engage in sexual activity of any kind with a partner and / or by yourself (masturbation)?

No sexual activity of any kind with a partner and / or by myself (masturbation) ➔*Please complete SN1-15*
Sexual activity with a partner only ➔*Please complete SA1-15*
Sexual activity by yourself only ➔*Please complete SA1-15*
Sexual activity both with a partner and by yourself ➔*Please complete SA1-15*

Non-sexually active women only

Now think about any occasion over the last 4 weeks when sexual activity was a possibility but you did not have sexual activity.

Over the past 4 weeks, I did not have sexual activity or intercourse because:

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
SN1 I rarely felt aroused ('turned on')	5	4	3	2	1
SN2 I experienced a low level of arousal ('turn on')	5	4	3	2	1
SN3 I did not fee confident that I can become sexually aroused	5	4	3	2	1
SN4 I was not satisfied with my level of sexual arousal	5	4	3	2	1
SN5 I rarely got lubricated ('wet')	5	4	3	2	1
SN6 I find it hard to become lubricated ('wet')	5	4	3	2	1
SN7 I did not stay lubricated ('wet') until the end of sexual activity or intercourse	5	4	3	2	1
SN8 It was hard to stay lubricated ('wet') until the end of sexual activity or intercourse	5	4	3	2	1
SN9 I rarely achieve orgasm	5	4	3	2	1
SN10 I find it difficult to achieve orgasm	5	4	3	2	1
SN11 I was not satisfied with my ability to achieve orgasm	5	4	3	2	1
SN12 I feel pain or discomfort during sexual intercourse	5	4	3	2	1
SN13 I feel pain or discomfort after sexual intercourse	5	4	3	2	1
SN14 I feel intense and severe pain or discomfort during or after sexual intercourse	5	4	3	2	1
SN15 I was not satisfied with the amount of emotional closeness during sexual activity between me and my partner	5	4	3	2	1

➔ *Please skip SA1-15 questions and continue to 9.*

Sexually active women only

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

SA1 Over the past 4 weeks, how often did you feel sexually aroused ('turned on') during sexual activity or intercourse?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

SA2 Over the past 4 weeks, how would you rate your level of sexual arousal ('turn on') during sexual activity or intercourse?

Very high	High	Moderate	Low	Very low or none at all
5	4	3	2	1

SA3 Over the past 4 weeks, how confident were you about becoming sexually aroused during sexual activity or intercourse?

Very high confidence	High confidence	Moderate confidence	Low confidence	Very low or no confidence
5	4	3	2	1

SA4 Over the past 4 weeks, how often were you satisfied with your arousal ('turn on') during sexual activity or intercourse?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

SA5 Over the past 4 weeks, how often did you become lubricated ('wet') during sexual activity or intercourse?

Almost always or always	Not always but artificial lubricants were helpful in aiding my sexual activity or intercourse	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
6	5	4	3	2	1

SA6 Over the past 4 weeks, how difficult was it to become lubricated ('wet') during sexual activity or intercourse?

Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Difficult, but artificial lubricants were helpful in aiding my sexual activity or intercourse	Not difficult
1	2	3	4	5	6

SA7 Over the past 4 weeks, how often did you maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

Almost always or always	Not always but artificial lubricants were helpful in aiding my sexual activity or intercourse	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
6	5	4	3	2	1

SA8 Over the past 4 weeks, how <u>difficult</u> was it to maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Difficult, but artificial lubricants were helpful in aiding my sexual activity or intercourse	Not difficult
1	2	3	4	5	6

SA9 Over the past 4 weeks, when you had sexual stimulation or intercourse, how <u>often</u> did you reach orgasm?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

SA10 Over the past 4 weeks, when you had sexual stimulation or intercourse, how <u>difficult</u> was it for you to reach orgasm (climax)?

Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult
1	2	3	4	5

SA11 Over the past 4 weeks, how <u>satisfied</u> were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

SA12 Over the past 4 weeks, how <u>often</u> did you experience discomfort or pain during vaginal penetration?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
1	2	3	4	5

SA13 Over the past 4 weeks, how <u>often</u> did you experience discomfort or pain following vaginal penetration?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
1	2	3	4	5

SA14 Over the past 4 weeks, how would you rate your <u>level (degree)</u> of discomfort or pain during or following vaginal penetration?

Very high	High	Moderate	Low	Very low or none at all
1	2	3	4	5

SA15 Over the past 4 weeks, how <u>satisfied</u> have you been with the amount of emotional closeness during sexual activity between you and your partner?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

➔ *Please continue to 9 (below)*

Core questions – all women to answer

9. Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied	No partner
5	4	3	2	1	(Missing)

10. Over the past 4 weeks, how satisfied have you been with you overall sexual life?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

11. Over the past 4 weeks, how well were your sexual needs fulfilled?

Not at all	Slightly	Moderately	Very much	Extremely
1	2	3	4	5

12. Over the past 4 weeks, how would you rate your sex life?

Very poor	Poor	Neither good nor poor	Good	Very good
1	2	3	4	5

Over the past 4 weeks, how often did you feel distressed, bothered or frustrated about your...

	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
13. Sexual desire	1	2	3	4	5
14. Sexual arousal	1	2	3	4	5
15. Ability to orgasm	1	2	3	4	5
16. Ability to get lubricated ('wet')	1	2	3	4	5
17. Level of pain during sexual activity	1	2	3	4	5
18. Your sexual life	1	2	3	4	5

Supplementary partner questions

Over the past 4 weeks, my sexual functioning has been influenced by:

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
19. The availability of a partner	1	2	3	4	5
20. My partner's desire for sex	1	2	3	4	5
21. My partner's sexual problems	1	2	3	4	5
22. My partner's response to my body after the breast cancer or treatment	1	2	3	4	5

7.7.1.7 Sexual Problems Scale (SPS)

During the past month,

	Not a problem	A little problem	Somewhat of a problem	Very much a problem
I had lack of interest in sex	1	2	3	4
I was unable to relax and enjoy sex	1	2	3	4
I had difficulty becoming sexually aroused	1	2	3	4
I had pain and discomfort with intercourse	1	2	3	4
I had difficulty having an orgasm	1	2	3	4
I did not feel satisfied after sex	1	2	3	4
I did not feel sexually attractive	1	2	3	4
I believed that I was not sexually attractive to my spouse/partner	1	2	3	4
I did not think my partner was interested in sex	1	2	3	4

7.7.1.8 Cancer Rehabilitation Evaluation System (CARES) Sexual Functioning Subscale

Below is a list of problem statements that describe situations and experiences of individuals who have had cancer. Read each statement and circle the number that describes how much each statement applies to you DURING THE LAST FOUR WEEKS

	Not at all	A little	A fair amount	Much	Very much
I do not feel sexually attractive	1	2	3	4	5
I do not feel my partner finds me sexually attractive	1	2	3	4	5
I am not interested in having sex	1	2	3	4	5
I do not think my partner is interested in having sex	1	2	3	4	5

7.7.2 Time 2 Survey

7.7.2.1 Female Sexual Function Index, Breast Cancer Adaptation (FSFI-BC)

Many women experience changes in sexual functioning following diagnosis and treatment of breast cancer. Compared to my sexual functioning prior to breast cancer diagnosis and treatment:

	Decreased a lot	Decreased a little	Stayed the same	Increased a little	Increased a lot
1. My sexual desire	1	2	3	4	5
2. My arousal	1	2	3	4	5
3. My ability to get lubricated	1	2	3	4	5
4. My ability to reach orgasm	1	2	3	4	5
5. The satisfaction with my sex life	1	2	3	4	5

The following questions ask about your sexual feelings and responses during the past 4 weeks. In answering these questions the following definitions apply:

SEXUAL ACTIVITY can include caressing, foreplay, masturbation and vaginal intercourse

SEXUAL INTERCOURSE is defined as penile penetration (entry) of the vagina

SEXUAL STIMULATION includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

6. Over the past 4 weeks, how often did you feel sexual desire or interest?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

7. Over the past 4 weeks, how would you rate your level (degree) of sexual desire or interest?

Very high	High	Moderate	Low	Very low or none at all
5	4	3	2	1

8. Over the past 4 weeks, did you engage in sexual activity of any kind with a partner and / or by yourself (masturbation)?

No sexual activity of any kind with a partner and / or by myself (masturbation) ➔*Please complete SN1-15*
Sexual activity with a partner only ➔*Please complete SA1-15*
Sexual activity by yourself only ➔*Please complete SA1-15*
Sexual activity both with a partner and by yourself ➔*Please complete SA1-15*

Non-sexually active women only

Now think about any occasion over the last 4 weeks when sexual activity was a possibility but you did not have sexual activity.

Over the past 4 weeks, I did not have sexual activity or intercourse because:

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
SN1 I rarely felt aroused ('turned on')	5	4	3	2	1
SN2 I experienced a low level of arousal ('turn on')	5	4	3	2	1
SN3 I did not fee confident that I can become sexually aroused	5	4	3	2	1
SN4 I was not satisfied with my level of sexual arousal	5	4	3	2	1
SN5 I rarely got lubricated ('wet')	5	4	3	2	1
SN6 I find it hard to become lubricated ('wet')	5	4	3	2	1
SN7 I did not stay lubricated ('wet') until the end of sexual activity or intercourse	5	4	3	2	1
SN8 It was hard to stay lubricated ('wet') until the end of sexual activity or intercourse	5	4	3	2	1
SN9 I rarely achieve orgasm	5	4	3	2	1
SN10 I find it difficult to achieve orgasm	5	4	3	2	1
SN11 I was not satisfied with my ability to achieve orgasm	5	4	3	2	1
SN12 I feel pain or discomfort during sexual intercourse	5	4	3	2	1
SN13 I feel pain or discomfort after sexual intercourse	5	4	3	2	1
SN14 I feel intense and severe pain or discomfort during or after sexual intercourse	5	4	3	2	1
SN15 I was not satisfied with the amount of emotional closeness during sexual activity between me and my partner	5	4	3	2	1

➔ *Please skip SA1-15 questions and continue to 9.*

Sexually active women only

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

SA1 Over the past 4 weeks, how often did you feel sexually aroused ('turned on') during sexual activity or intercourse?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

SA2 Over the past 4 weeks, how would you rate your level of sexual arousal ('turn on') during sexual activity or intercourse?

Very high	High	Moderate	Low	Very low or none at all
5	4	3	2	1

SA3 Over the past 4 weeks, how confident were you about becoming sexually aroused during sexual activity or intercourse?

Very high confidence	High confidence	Moderate confidence	Low confidence	Very low or no confidence
5	4	3	2	1

SA4 Over the past 4 weeks, how often were you satisfied with your arousal ('turn on') during sexual activity or intercourse?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

SA5 Over the past 4 weeks, how often did you become lubricated ('wet') during sexual activity or intercourse?

Almost always or always	Not always but artificial lubricants were helpful in aiding my sexual activity or intercourse	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
6	5	4	3	2	1

SA6 Over the past 4 weeks, how difficult was it to become lubricated ('wet') during sexual activity or intercourse?

Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Difficult, but artificial lubricants were helpful in aiding my sexual activity or intercourse	Not difficult
1	2	3	4	5	6

SA7 Over the past 4 weeks, how often did you maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

Almost always or always	Not always but artificial lubricants were helpful in aiding my sexual activity or intercourse	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
6	5	4	3	2	1

SA8 Over the past 4 weeks, how <u>difficult</u> was it to maintain your lubrication ('wetness') until completion of sexual activity or intercourse?

Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Difficult, but artificial lubricants were helpful in aiding my sexual activity or intercourse	Not difficult
1	2	3	4	5	6

SA9 Over the past 4 weeks, when you had sexual stimulation or intercourse, how <u>often</u> did you reach orgasm?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
5	4	3	2	1

SA10 Over the past 4 weeks, when you had sexual stimulation or intercourse, how <u>difficult</u> was it for you to reach orgasm (climax)?

Extremely difficult or impossible	Very difficult	Difficult	Slightly difficult	Not difficult
1	2	3	4	5

SA11 Over the past 4 weeks, how <u>satisfied</u> were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

SA12 Over the past 4 weeks, how <u>often</u> did you experience discomfort or pain during vaginal penetration?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
1	2	3	4	5

SA13 Over the past 4 weeks, how <u>often</u> did you experience discomfort or pain following vaginal penetration?

Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
1	2	3	4	5

SA14 Over the past 4 weeks, how would you rate your <u>level (degree)</u> of discomfort or pain during or following vaginal penetration?

Very high	High	Moderate	Low	Very low or none at all
1	2	3	4	5

SA15 Over the past 4 weeks, how <u>satisfied</u> have you been with the amount of emotional closeness during sexual activity between you and your partner?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

➔ *Please continue to 9 (below)*

Core questions – all women to answer

9. Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied	No partner
5	4	3	2	1	(Missing)

10. Over the past 4 weeks, how satisfied have you been with you overall sexual life?

Very satisfied	Moderately satisfied	About equally satisfied and dissatisfied	Moderately dissatisfied	Very dissatisfied
5	4	3	2	1

11. Over the past 4 weeks, how well were your sexual needs fulfilled?

Not at all	Slightly	Moderately	Very much	Extremely
1	2	3	4	5

12. Over the past 4 weeks, how would you rate your sex life?

Very poor	Poor	Neither good nor poor	Good	Very good
1	2	3	4	5

Over the past 4 weeks, how often did you feel distressed, bothered or frustrated about your...

	Almost always or always	Most times (more than half the time)	Sometimes (about half the time)	A few times (less than half the time)	Almost never or never
13. Sexual desire	1	2	3	4	5
14. Sexual arousal	1	2	3	4	5
15. Ability to orgasm	1	2	3	4	5
16. Ability to get lubricated ('wet')	1	2	3	4	5
17. Level of pain during sexual activity	1	2	3	4	5
18. Your sexual life	1	2	3	4	5

Supplementary partner questions

Over the past 4 weeks, my sexual functioning has been influenced by:

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
19. The availability of a partner	1	2	3	4	5
20. My partner's desire for sex	1	2	3	4	5
21. My partner's sexual problems	1	2	3	4	5
22. My partner's response to my body after the breast cancer or treatment	1	2	3	4	5

7.7.2.2 Acceptability questions

Please rate the following statements about the questions that you answered so far today. All questions belong to a single questionnaire

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I felt comfortable answering the questions	1	2	3	4	5
The questions were easy to complete	1	2	3	4	5
The questions were relevant to my experiences	1	2	3	4	5
The questionnaire above was about the right length	1	2	3	4	5

7.7.2.3 Changes questions

Over the past 2 weeks, my

	Has increased	Stayed the same	Has decreased
Desire	1	2	3
Arousal	1	2	3
Lubrication	1	2	3
Orgasm	1	2	3
Pain	1	2	3
Satisfaction with sex life	1	2	3
Distress over sex life	1	2	3