Cancer Research Consortium of West Michigan
P: 616.391.1230 | 800.336.6299 | www.crcwm.org

FAST FACTS

WF 2202: Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education (SHINE) Trial

ELIGIBILITY CRITERIA

1. 0 Inclusion Criteria

1.1 History of Stage 0-III breast cancer diagnosis. History of non-breast malignancies are permitted.

1.2 ≥12 weeks following last primary cancer treatment. For this protocol, primary cancer treatments are defined as chemotherapy, cytotoxic antibody-drug conjugates, checkpoint inhibitors, radiation, and surgical procedures intended to remove malignant tissue. Ongoing adjuvant endocrine therapy (e.g.,tamoxifen, aromatase inhibitors), adjuvant cdk 4/6-inhibitors (e.g., abemaciclib), HER2-based Monoclonal antibody therapy (e.g., trastuzumab, pertuzumab), HER2 targeted Tyrosine Kinase inhibitors (e.g., neratinib), and/or pending breast reconstructive surgery are allowed. (There is no upper limit on time since treatment. This is due to criterion 4.1.7 below – participants must endorse current sexual morbidity that they believe is related to their breast cancer. Breast cancer-related sexual morbidity often persists, or even worsens, years following treatment.)

1.3 Age ≥18 years at the time of study enrollment.

Items below will be asked on the *Self-reported Eligibility Screener* to the patient directly:

1.4 Cisgender female (i.e., assigned female at birth, female gender identity);

1.5 Currently in an intimate relationship, as reported on the PROMIS SexFS screener1 (this relationship may be with an individual of any sex and gender identity);

1.6 Endorse being at least "somewhat" bothered by ≥1 of the following during the last 30 days: (lack of) interest in sexual activity, vaginal dryness, pain during sexual activity, or (in)ability to orgasm, as reported on the PROMIS SexFS Bother Regarding Sexual Function1 screener;

1.7 Endorse that ≥1 of the bothersome sexual symptoms, from the PROMIS SexFS Bother Regarding Sexual Function1 screener (see 4.1.6) is related to their breast cancer;

1.8 Has a working email address (or willing to create one) and receive emails from the study.

2.0 Exclusion Criteria

2.1 Planned cancer treatment for residual, progressive, or recurrent disease within the 24 weeks following enrollment (defined as chemotherapy, cytotoxic antibody-drug conjugates, checkpoint inhibitors, radiation, and/or surgical procedures intended to remove malignant tissue). Ongoing adjuvant endocrine therapy (e.g., tamoxifen, aromatase inhibitors), adjuvant cdk 4/6-inhibitors (e.g., abemaciclib), HER2-based Monoclonal antibody therapy (e.g.,

trastuzumab, pertuzumab), HER2 targeted Tyrosine Kinase inhibitors (e.g., neratinib), and/or pending breast reconstructive surgery are allowed.

2.2 Unable to read and comprehend English (SHINE intervention currently only available in English) as indicated by being unable to complete the Self-reported Screening Questionnaire independently.

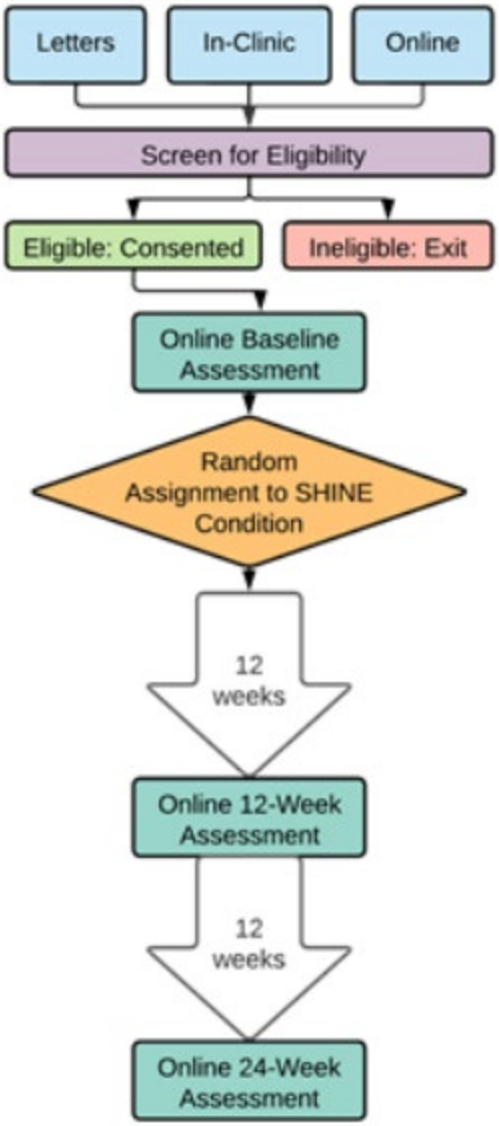
Items below will be asked on the *Self-reported Eligibility Screener* to the patient directly:

2.3 Does not have reliable access to Internet (e.g., by home broadband, public network, personal data plan) by computer, tablet, smartphone etc. and is not willing to participate in the tablet lending program for this study.

2.4 Recent serious mental illness, as defined by reporting an inpatient psychiatric hospitalization within the past 12 months.

2.5 Currently participating in couple, marital, or sex therapy.

2.6 Currently pregnant (Pregnant women are excluded from this study because childbirth is accompanied by significant biological, psychological, and environmental changes that alter a woman's sexual functioning. Intervention content may not be medically appropriate for women who have recently given birth, given that medical providers commonly recommend that women avoid sexual contact for at least four to six weeks post-partum while healing.).


Letters
In-Clinic
Online
Screen for Eligibility
Eligible: Consented
Ineligible: Exit
Online Baseline Assessment
Random Assignment to SHINE Condition
12 weeks
Online 12-Week Assessment
12 weeks
Online 24-Week Assessment