

Title: Web-Based Communication Education for Breast Cancer Survivorship Care

Date approved by Georgetown University Institutional Review Board: 1/30/2017

NCT Number: N/A

Statistical Analysis Plan

The LA Registry has approximately 1,209 Chinese women (age 18-85) who were diagnosed with stage 0-III breast cancer from 2012 through 2014. About 77% (n= 931) are Chinese-speaking immigrants per our preliminary data. Assuming a 28% response rate derived from our prior participation rate (35%) and 80% of the sample expressing interest in a web intervention, we expect approximately 261 women will provide consent for participation. Thus, it is highly feasible to achieve our accrual goal of 118 participants. Chinese American breast cancer incidence rates are increasing meaning that the number of potential participants from the LA Registry should increase.

For Aim 2, assuming that the intervention will increase Chinese survivors' mean communication score from 32 (SD=5.7) to 35.5 points, closer to the NHW's mean score=37 (SD=4.4), we will need a final sample of 90 to detect the 3.5 point difference between the two study groups (n=45 per group, a 1:1 ratio; 80% power, 2-sided, $p<.05$) after accounting for a 10% attrition rate and 85% of women visiting doctors at T2. With 90 women, we will also be 80% powered to detect an increase in perceived control and self-efficacy with Cohen's (d) =0.65 and 0.6, respectively. For Aim 3, we are aware that some women may just visit their doctors at the T2 follow-up. Thus, this pilot trial may not show significant changes in distal outcomes. Moreover, the final 90 women who complete the T2 assessment will allow for detection of a clinically meaningful increase in the PROMIS physical function baseline T score from 48 to 53 points (d=0.6, 80% power, 2-sided, $p<.05$). In this pilot trial, we are not powered to detect modest effect sizes; however, one of the central goals of this R21 study is to obtain data to determine the likely effect sizes for a larger RCT.