Mobile Apps to Reduce Distress in Breast Cancer Survivors using an Adaptive Design

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Aim1: Test the impact of the IntelliCare apps on reducing symptoms of depression and anxiety in breast cancer survivors.

We will compare the efficacy of the IntelliCare apps vs. app-delivered Patient Education in reducing symptoms of depression and anxiety from pre-intervention to post intervention and 6 and 12 month follow ups. To obtain the main effect of the IntelliCare apps on symptom reduction, it is important to account for the potential confound of added coaching that some of the low-engagers will receive. The impact of IntelliCare apps on depression and anxiety symptoms will be examined using a potential outcomes framework and marginal structural models (MSM).[124] Because all low-engagers of the IntelliCare apps will be re-randomized to receive either added coaching or no change, we are able to assign weights to assess the marginal mean for participants under the condition that nobody received added coaching, and compare it to the marginal mean for individuals that received app-delivered Patient Education. The IntelliCare condition will be estimated by using Inverse Probability of Treatment Weights.[125] Specifically, participants that received the IntelliCare apps will be assigned a weight of 2 if they were identified as low-engagers and then randomized to continue the apps with no change, and will be assigned a weight of 1 if they were not re-randomized (i.e., they were identified as high-engagers). Participants that were re-randomized to receive added coaching will be assigned a weight of 0 which negates their impact. This is done to account for the potential impact of added coaching on the efficacy of the IntelliCare apps.

After data is appropriately weighted, we will use a regression based approach for statistical hypothesis testing. We will use the mixed model repeated measures (MMRM) method for repeated measures models with weights as recommended for SMART designs. The weighted treatment and control means at baseline, post, 6m, and 12m will then be regressed as a function of treatment, time point, and treatment by time interaction. Using this model, we will be able to test for the presence of individual interaction effects. Statistical significance ($p<.05$) will imply differential change in symptoms of depression and anxiety due to the impact of the IntelliCare apps vs. app-delivered Patient Education at each time point.

Aim 2. Test the impact of added coaching on engagement with the IntelliCare apps.

The purpose of Aim 2 is to test whether coaching results in greater engagement with the IntelliCare apps. Therefore, app engagement is the outcome. We will examine three aspects of app engagement in separate analyses: app launches and number of days used. Medians, adjusted means, and interquartile ranges will be examined. MMRM with adjusted means will be used to evaluate whether added coaching led to increased app engagement with IntelliCare compared to no added coaching in weeks 2-8, for suboptimal engagers after week 1.