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

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Participants and recruitment: We will recruit 313 adult women diagnosed with breast cancer (stages 1-3) in the last 5 years (see Power analysis section in c.2.iii for justification of sample size). Only participants who screen high in symptoms of depression and/or anxiety will be enrolled. We will use both online and offline advertising, for recruitment including support from the Cancer Support Community online (https://www.cancersupportcommunity.org)

Inclusion criteria. (1) age ≥ 18 years;(2) 0-5 years post-diagnosis of Stage I, II, or III female breast cancer; (3) elevated symptoms of depression and/or anxiety as measured by the PHQ-8 (score ≥10) or GAD-7 (score ≥8).

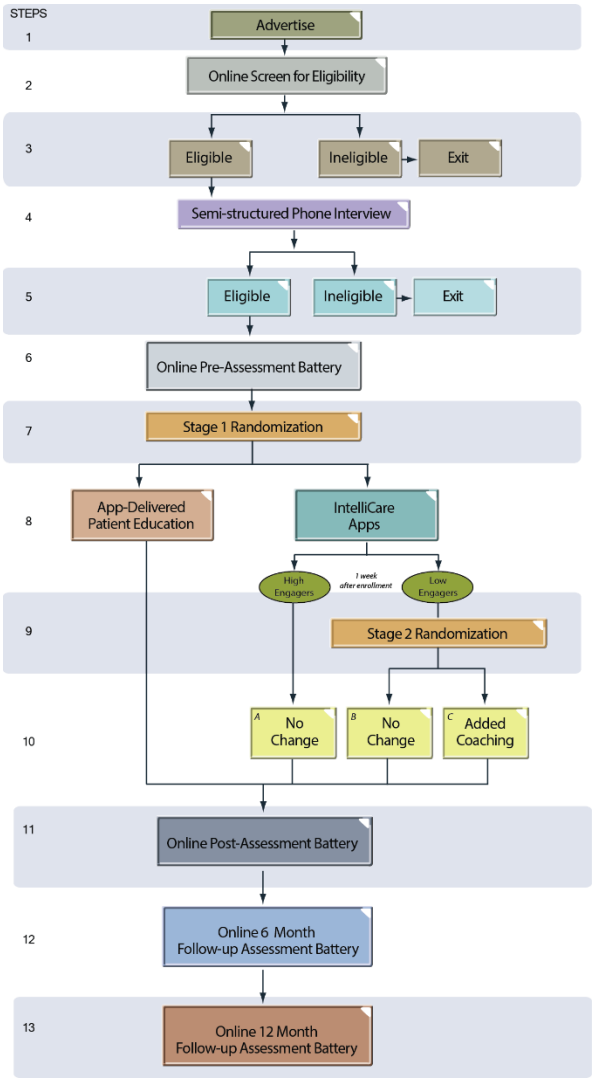
Exclusion criteria. (1) receiving or scheduled to initiate individual (1 on 1) treatment for depression and/or anxiety to avoid treatment interference (note, individuals will be permitted to enroll if they are taking antidepressant medication and have not had an appointment to adjust the dosage over the past 2 weeks); (2) mental health condition deemed to interfere with study procedures or put the participant at undue risk based on self-reported history of psychosis or bipolar disorder, or active suicidal ideation that necessitates more intense care as indicated from the Columbia-Suicide Severity Rating Scale (C-SSRS); (3) do not have an app-compatible phone (i.e., iOS 10.3 or later or Android 4.0.3 or later); and (4) cannot read and speak English (apps and coaching only available in English).

Survivors may be included if they are currently receiving or have concluded any cancer treatment (i.e., surgery, chemotherapy, radiation therapy, or hormonal therapy). Although we considered narrowing our criteria to exclude those treated with hormonal therapy or chemotherapy, given their impact on mood and their potential impact on app uptake, we sought to investigate the efficacy of IntelliCare for a broad population of breast cancer survivors to increase the generalizability of findings. We will assess treatment factors which will allow us to characterize our sample and to examine whether treatment factors are related to app usage. The process of randomization should distribute the cancer treatment factors evenly across the IntelliCare and Patient Education conditions, thereby reducing risk of confounding the impact of treatment on outcomes.

Procedure: Figure 1 depicts the flowchart of study procedures.

Screening, enrollment, and preassessment: Interested cancer survivors will see our advertisement (Step 1), and respond by either going to our website to read the study description details and/or calling a toll-free number to discuss the details with a member of the research staff. Then, if appropriate and motivated, individuals will be directed to complete a brief online interest screen (Step 2) which will be automatically stored and then reviewed by staff to determine initial eligibility (Step 3). Ineligible individuals will be informed that they do not qualify for the study. The study coordinator will speak by

phone (Steps 4 and 5) to individuals pre-eligible based on their screener results to inform them about the study, answer all study questions, ensure eligibility using the phone screen, review the consent form, and instruct participants about the online informed consent process. Online consent forms will be completed using the IRB-approved procedure for our other digital intervention studies. A detailed medical history of eligible participants will also be taken. Participants will then complete the online pre-assessment battery online (Step 6). It is estimated that the pre-assessment battery will take 45-60 minutes to complete.



Stage 1 Randomization: After completing the pre-assessment battery, participants will be randomized to 1 of 2 conditions: 1) IntelliCare apps; or 2) App-delivered Patient Education (Steps 7 and 8). Following the procedure in prior IntelliCare trials, participants will receive a brief (10 min) enrollment call to make sure they can download and use the apps. We will use an existing onboarding phone protocol from prior trials. Specifically, the protocol walks the user through downloading the apps from the Google Play or iTunes store, enter their Study ID, and allows participants to ask questions before accepting the app use permissions. These permissions must be accepted in order for the apps to work.

Stage 2 Randomization: After monitoring app use for the first week of enrollment, participants who received the IntelliCare apps and are low-engagers of the intervention will be randomly assigned to receive added coaching or no change (Steps 9 and 10). Breast cancer survivors receiving the app-delivered Patient Education (i.e., control condition) will not be re-randomized.

Post-assessment and follow-up assessments: At the start of week nine, regardless of intervention progress or experimental group, participants will be instructed to complete the online post-assessment battery (Step 11). The post-assessment is similar to the pre-assessment battery but also includes the intervention evaluation measures, as used in our previous digital intervention studies, which provide, in part, insight into the utility, preference, and perceived efficacy of the intervention. After completing the post-

assessment battery, individuals will have continued access to their assigned program. Those that received added coaching will no longer receive coaching after the start of week nine, but will continue to have access to the apps. This same assessment battery will be completed again at 6 month (Step 12) and 12 month (Step 13) follow-ups. Participants will receive $50 for completing the post, another $50 for completing the 6-month follow-up, and $100 for completing the 12-month follow up (total = $200 as online gift certificates).

We will also conduct semi-structured interviews at the start of week nine with participants randomized to receive IntelliCare. This will enable us to identify the key themes, if any, to guide potential tailoring of the IntelliCare apps for a future study that will compare the tailored apps against the standard (i.e., untailored) apps. Individual interviews will include questions on how the apps meet their needs as a breast cancer survivor and specific changes to the apps that would make them more applicable. Potential themes that may be expressed by survivors may include using specific breast cancer examples, modifications to app look and feel, language used throughout the app, or the need for a new app component like dealing with fatigue or survivorship care planning. Information gathered from the interviews will then be used to inform possible modifications of the apps for use in a future study. In addition, we will also assess participants' preferences to receiving coaching, if any, among the low-engagers who received coaching in the IntelliCare condition. Interviews will assess the appropriateness of the timing, duration, frequency, and usefulness of coaching calls, as well as ways to improve the content of coaching calls for breast cancer survivors.

Coaching. Low-engager individuals who are randomized to the added coaching condition will receive coaching in addition to the standard IntelliCare apps. Coaching will be provided throughout the 8-week intervention period to those assigned to this condition. A coaching manual was developed for the pilot study of the IntelliCare apps among breast cancer survivors, and was modelled on a manual developed and refined by co-Investigator Mohr and consultant Lattie. The manual is based on the Efficiency Model of Behavioral Intervention Technology Support.

Coaching is meant to support participants' utilization of the IntelliCare apps. Coaches target potential points at which users may fail to benefit from the program. These "failure points" include issues related to the usability of the program, engagement with it, fit of the program tool to one's needs, knowledge of how to use the program, and implementation failures (e.g. one practices the skills using the program tools, but does not use them in day to day life). Once a failure point is identified, the coach provides support to the user to help address the obstacles that may be in the way of using the application. In keeping with prior studies, coaches will not be providing traditional counseling or psychotherapy. Rather, the coaching is focused on identifying and addressing barriers to application utilization. An initial 30-45 minute coaching call will focus on orienting participants to using the apps, setting expectations of the coach's role, assessing how the apps may meet participants' needs, and building rapport. This

will be done in a semi-structured interview format. Participants will also be encouraged to contact coaches at any time, using email or text, with any app-related questions. Following the initial coaching call, participants will receive a text message every week from the coach to remind them to download and try 1-2 new IntelliCare apps. We will conduct fidelity assessments based on procedures from prior IntelliCare trials. Bachelor's degree-level coaches will be trained and monitored by the PI (Dr. Chow) with the support of consultant Lattie, who each have a PhD in clinical psychology and over 8 years of experience in conducting psychological assessments and psychotherapy. Coaches will receive a detailed coaching manual and will attend weekly supervision meetings throughout the trial. Coaches will also be trained to use an existing researcher-facing web portal, which has been used in multiple IntelliCare trials, to track app usage as well as send and receive text messages.