PROTCOL TITLE:

Addressing Non-Initiation of Recommended Adjuvant Endocrine Therapy with a Culturally Informed Intervention

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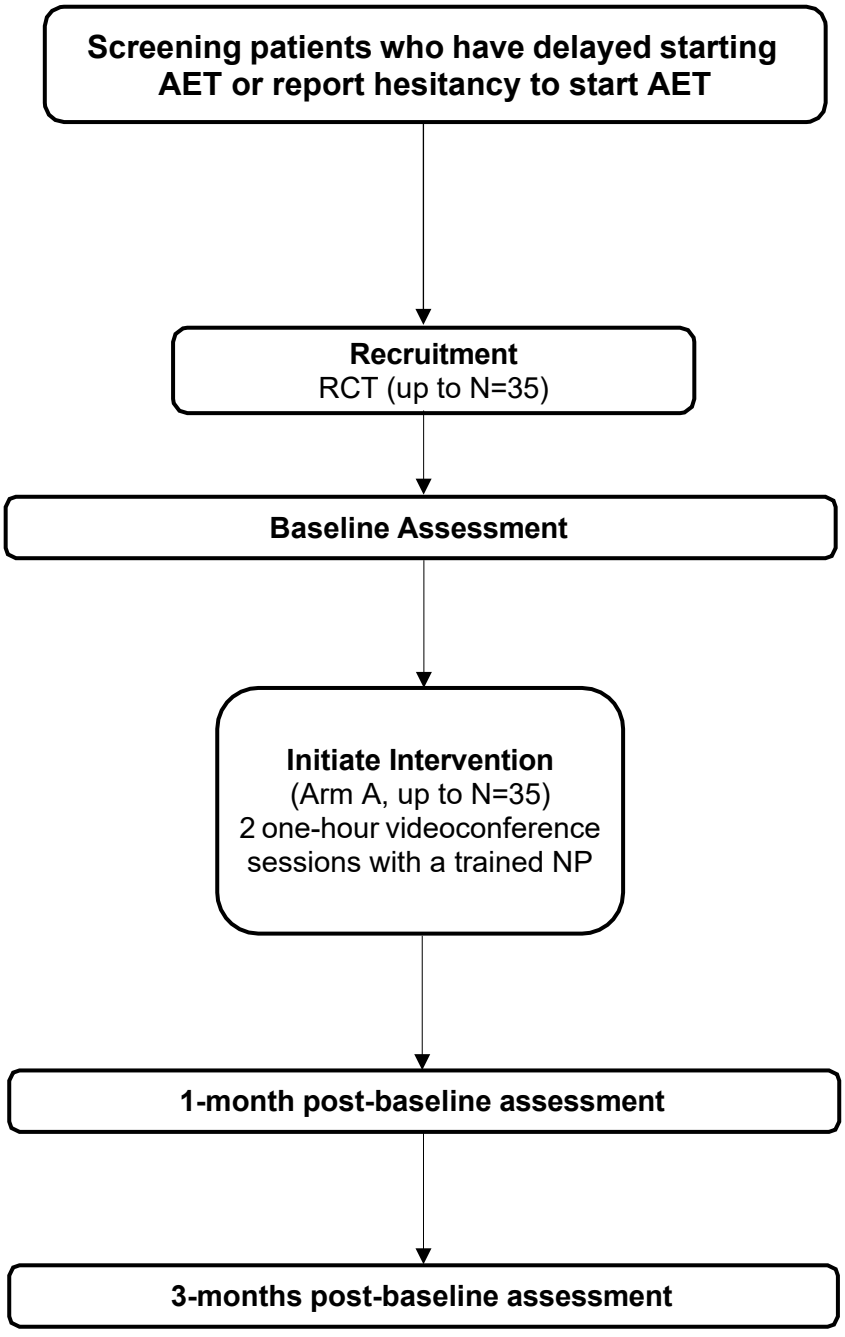
SECTION 1: Phase 2 RCT Study Protocol Schema



SECTION 2: Body of Protocol

1.0 Introduction

1.1 Overview

The present protocol proposes to conduct a single-arm pilot trial to examine the feasibility and acceptability of a patient-centered, evidence-based, culturally competent, tailored intervention to encourage breast cancer survivors who have not begun taking adjuvant endocrine therapy (AET) to initiate the medication. Phase 1 (21-331) includes intervention development based on the literature, behavior change theory (described below), expert input from breast oncologists and nurses, and semi-structured interviews with a diverse sample of BCS who delayed AET initiation or are hesitant to start (N=10). In Phase 2 of the study, we are seeking to evaluate the feasibility and acceptability of the 2-session intervention that we develop with purposeful recruitment of racial/ethnic minorities. AET initiation will be measured by a self-report questionnaire. Participants will complete assessments at baseline, 1-month, and 3-months post-baseline measuring beliefs about AET necessity, satisfaction with patient-physician communication, perceived social support and quality of life. The proposed project is funded by an Electronic Space Systems Corporation (ESSCO) MGH Breast Cancer Research Fund Grant.

1.2 Background and Rationale

AET is critical for lowering risk of recurrence and preventing second primary breast cancers in stage 0-IIIB hormone sensitive breast cancer survivors (BCS). Female breast cancer is the most commonly diagnosed cancer in the U.S.; one in eight women (12%) will develop breast cancer in her lifetime.[1] Approximately 60-75% of breast malignancies are hormone sensitive[1] and treated with AET to inhibit cancer growth, reducing recurrence and mortality by 50% and 29%, respectively.[2] Surprisingly, despite overwhelming clinical benefits and life-saving potential, initiation of AET among BCS is suboptimal, with several failing to initiate[3] or delaying initiation.[4] On self-report, non-initiation rates range from 12.0%-19%,[3,5] while objective measures such as pharmacy refill and medical record abstraction suggest that up to 30% of BCS do not initiate AET as recommended.[6]

BCS of a racial or ethnic minority are disproportionately less likely to initiate AET. African American/Black and Hispanic/Latina women have a higher mortality risk compared to Non-Hispanic Whites; with a 1.4-2.4-fold greater risk of breast cancer specific mortality.[7] This disparity may be attributed, in part, to the disparity in AET initiation, with Black and Hispanic/Latina BCS being significantly less likely to initiate AET than White BCS.[8,9,10] Although the risk of breast cancer mortality for Asian American women is variable and AET initiation in Asian American women is not well understood, some research has found that Asian American women are also less likely to initiate AET.[9,10] AET use is critical and associated with a 29% relative risk reduction in mortality.[1] Patient deviations from guideline concordant care with recommended AET are associated with recurrence, mortality, and poor patient-provider relationships. [11]

AET initiation is a modifiable health behavior with established predictors, with some being more salient for minority BCS. Adherence to guideline concordant care is the single most modifiable factor that influences treatment outcomes for BCS.[12] Modifiable factors associated with non-initiation of AET include (1) low perceived social support and poor communication with clinicians, (2) negative beliefs about treatment efficacy, and (3) fears of toxicities. First, BCS who report a lower quality of communication with their physicians, less social support and greater difficulty making decisions around AET treatment are less likely to initiate.[3,13] Notably, quality of communication about AET and clinician trust is rated lower among Black BCS than Whites.[14] Among low-income Latina women, patient-centered communication may increase AET use.[15] Second, non-initiators are more likely to hold negative beliefs about therapeutic efficacy and less favorable attitudes towards AET.[3] Across all racial and ethnic groups, discontinuation is associated with questions about "whether AET is helping."[16] Third, adverse effects (e.g., joint pain, hot flashes, sleep difficulties) are common with AET and patients who express greater fears about these side effects are less likely to initiate.[3] While fears of side effects are present across all racial/ethnic groups, one study suggested that side effects were the most cited barrier to AET use among Hispanic patients.[9] In addition, BCS who report receiving inadequate information about managing side effects are less likely to initiate.[16] Ultimately, poor clinician-patient

communication and social support, doubts about efficacy, and fears of side effects are modifiable contributors to AET initiation, and certain barriers are more pronounced in racial and ethnic minorities.

Interventions to improve initiation to AET are nonexistent, needed, and should be culturally sensitive. Despite some identified barriers to AET initiation, there are no existing interventions to increase initiation or address the racial/ethnic disparity in AET use. However, there is a small body of work investigating interventions to improve *adherence* (taking medication as directed) for patients already taking AET. A meta-analysis in 2019 identified four randomized controlled trials of interventions to improve AET adherence, with education delivery as the most common intervention and, not surprisingly, only one demonstrating a significant effect on adherence.[17] Absolutely no studies targeting AET use have incorporated cultural modifications[17], a necessity to ensure adaptation by racial and ethnic minority groups and to strengthen intervention effects on health behavior change.[18] Another meta-analysis identified eight intervention studies to improve adherence to AET with an overall null effect across interventions.[19] However, a sensitivity analysis showed that interventions using *bidirectional communication* were efficacious compared to those relying on one-way communication of information. This suggests that future interventions should enhance patient engagement and promote interactive discussion.

To be effective, interventions to improve initiation to AET for BCS should be multimodal, bidirectional, culturally competent, and convenient, targeting modifiable factors beyond the provision of information.[20] Most oncology clinicians will schedule a visit 3-4 months after prescribing AET in order to assess whether the patient has initiated AET and to discuss how they are tolerating the medication. It is at this visit that providers may discover that the patient has not started taking the medication. While this may be a helpful check-in for some, literature suggests that successful interventions should offer: a) support earlier on,[13] b) bidirectional communication with clinicians,[3,19] c) evidence-based techniques to address negative beliefs about AET efficacy, d) information on expectations and management of side effects,[3,16] and e) culturally-sensitive problem-solving.[18] For example, in the breast cancer setting, encouraging patient participation has been shown to improve comprehension and treatment satisfaction.[21] As cultural beliefs influence decisions to start AET, culturally competent communication and problem-solving should address these beliefs and barriers.[22] In addition, treatment satisfaction, including communication with clinicians and nurses, predicts better adherence to oral anti-cancer therapy.[23] Research also suggests that oncology nurses should be involved in implementing clinical interventions to manage barriers to AET adherence such as concerns about side effects,[24] and that nursing involvement has the potential to prevent early disruptions in adherence to guideline concordant care[25] by facilitating shared decision-making,[24] discussing benefits and concerns of AET, and providing side-effect coping strategies.[26] In summary, to be efficacious, interventions targeting non-initiation should include oncology nurses, be culturally competent, and address modifiable barriers such as provider and social support, beliefs about therapeutic efficacy in recurrence prevention, and concerns about side effects.

To address this timely public health concern, the proposed study employs a two-phase mixed-methods design <u>to develop and test a culturally competent, evidence-based, brief, two-session, nurse-led intervention to promote AET initiation in a diverse sample of early-stage, hormone receptor-positive BCS who have delayed initiation or are hesitant to start.</u> Phase 1 (21-331) included intervention development based on the literature, behavior change theory (described below), expert input from breast oncologists and nurses, and semi-structured interviews with a diverse sample of BCS who delayed AET initiation or are hesitant to start (N=10). Phase 2 will be a single-arm pilot feasibility trial (up to N=35) of this intervention with purposeful recruitment of racial/ethnic minorities. AET initiation will be measured by a self-report questionnaire for the pilot study. Participants will complete assessments at baseline, 1-month, and 3-months post-baseline measuring beliefs about AET necessity, satisfaction with patient-physician communication, perceived social support, and quality of life.

Conceptual Framework

The proposed aims are based on National Institutes of Health (NIH) guidelines for behavioral intervention development: The Obesity-Related Behavioral Intervention Trials (ORBIT) Model. The ORBIT model emphasizes 1) designing the intervention based on drivers of behavior that are treatment targets and refining practical intervention aspects (i.e., mode of delivery, duration) using mixed-methods such as qualitative (semi-structured interviews) in addition to quantitative data (satisfaction measures); and 2) conducting a feasibility pilot study to justify an efficacy trial. The Social Ecological Model, which maintains that factors at the individual, interpersonal, and community, and societal level influence health behaviors, will provide a framework for developing an intervention that addresses culture-specific barriers to AET initiation.[27]

1.3 Preliminary Studies

A subgroup of BCS does not initiate recommended AET. Dr. Jacobs is currently conducting a National Cancer Institute-funded study to develop and test an evidence-based, psychosocial, telehealth intervention for adherence, symptom management, and distress in early-stage BCS taking AET.[28] The current RCT enrollment rate is 72%. A review of the Electronic Health Record (EHR) in the context of our current study revealed 75 BCS who had not initiated recommended AET. Documentation indicated that women did not start due to concerns about side effects or fears of long-term health consequences. These BCS are ineligible for the adherence study, and would be eligible for the proposed study.

Adherence is strongly associated with satisfaction with clinician communication. In a prospective longitudinal study, our research group identified factors associated with adherence to oral anti-cancer therapy over time including improved satisfaction with clinician communication and treatment (B = 0.73; 95% CI, 0.49 to 0.98), reduced perceived burden on others (B = -0.92; 95% CI, -1.76 to -0.09), and reduced symptom distress (B = -0.79; 95% CI, -1.41 to -0.18).[23]

Adherence to oral anti-cancer therapy is associated with symptom burden. In a subsequent RCT funded by the Patient Centered Outcomes Research Institute (PCORI), we reported that patients (N=181) took only 85.6% of their oral therapy according to an electronic pill cap and bottle, and that patients with greater cancer-related symptom severity (e.g., fatigue, sleep, memory problems, distress) had lower adherence (r=-0.20, p=.020) and worse quality of life (r=-.67, p<.0001), highlighting the importance of enhancing adherence and managing symptoms and side effects.[29]

Interventions to foster initiation and adherence to AET are lacking. To assess the need for interventions to improve adherence to oral anti-cancer therapy, we published a systematic review which revealed only three RCTs targeting AET adherence and no efficacious interventions.[30]

Patients with early-stage breast cancer can benefit from interventions. Dr. Jacobs's previous work demonstrates that a skills-based intervention such as Cognitive-Behavioral Stress Management can improve long-term clinical outcomes,[31] depression, and QOL for BCS.[32] Approximately one third of this sample was a racial or ethnic minority.

Summary. There is a subset of BCS that does not initiate AET as recommended. We know that *adherence* is related to modifiable factors including clinician communication, symptom severity, and concerns about side effects. Interventions are needed to improve patient adherence to guideline concordant care with AET, and we have had success in administrating skills-based interventions targeting modifiable behaviors in early-stage breast cancer with diverse patients. The current study proposes to build on this evidence by developing and testing a brief, individualized nurse-led intervention to increase *initiation* of AET in early-stage, hormone sensitive BCS.

1.4 Innovation of Proposed Study

This research project aims to reduce risk of recurrence and prevent second primary breast cancer by increasing initiation of AET for BCS who have failed or delayed AET initiation or are hesitant to start, with particular

attention to Black, Hispanic/Latina and Asian American BCS. The data from this Phase 2 single-arm pilot trial to test a behavioral intervention developed using feedback from Phase 1 (21-331) to improve initiation, will be used to apply for an NIH grant to conduct a full-scale efficacy trial of the intervention. This is an area of important clinical investigation that does not necessitate a new treatment or technology, but rather points to the critical need to improve how and whether patients engage with an efficacious, life-saving therapy. In the short-term, this study has the potential to improve understanding of AET need and efficacy and increase initiation by mitigating barriers and enhancing self-efficacy. To minimize burden and increase access, we propose to deliver the intervention via ZOOM™, a HIPAA-secure Massachusetts General Hospital (MGH)-approved software**.** The study staff may also administer these sessions in person of via phone if necessary. This intervention has minimal risk and is likely to improve patient satisfaction with communication with clinicians and management of AET-related side effects. In the long-term, this study may improve patient outcomes by preventing second primary tumors, recurrence, and disease-related mortality while promoting the quality of life of BCS and reducing the racial and ethnic disparity in breast cancer outcomes.

2.0 Objectives

- Aim 1: To examine the feasibility and acceptability of the brief nurse-led intervention in BCS who have delayed initiation of AET or are hesitant to start (up to N=35) and refine the intervention using qualitative and quantitative feedback.

  Hypothesis: The study will be feasible, defined by enrollment (rate>50%), retention (completion rate>70%) and attendance (≥70% of participants completing at least one session). The study will be acceptable as demonstrated by >75% of participants reporting average satisfaction scores greater than the mid-point of the Client Satisfaction Questionnaire (CSQ).

- Aim 2: To assess intervention-related changes in primary and secondary outcomes at one- and three-months post-baseline.
  Hypothesis*:* Following the intervention, BCS will be more likely to have started their AET. We will explore changes in satisfaction with patient-physician communication, perceived social support, self-efficacy for symptom management, and quality of life.

3.0 Research Subject Selection

3.1 Partial waiver of HIPAA Authorization

We request a partial waiver of HIPAA Authorization in order for our team to perform an initial screening process that requires review of the electronic medical record. This partial waiver is being requested to allow the research team to screen the oncology clinic schedules and identify potential study participants from a minimal chart review. In accordance with the DF/HCC policy: (1) this Waiver is being sought solely to review Protected Health Information as necessary to prepare a research protocol; (2) the Waiver will not include removing Protected Health Information from the Covered Entity by the researcher, and (3) the Protected Health Information for which we are requesting access is necessary for research purposes.

For individuals who provide verbal consent to participate in the study, we will obtain HIPAA authorization, as described in section 4.2 (Informed Consent Process).

Table 1. **Inclusion Criteria**
1. Female
2. Age 21 or older

3. Diagnosis of early-stage (Stage I-IIIB), hormone receptor-positive breast cancer
4. Recommended to start AET at least 3 weeks prior and not currently taking AET OR recommended to start AET in the future and reports hesitations to start AET as determined by a score of >/= 4 (range =0-10) when asked "How hesitant are you about starting your recommended hormonal therapy? (0=Not at all hesitant and 10 = Extremely hesitant)"
5. Ability to read and respond in English or Spanish
6. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
7. For at least 10 participants, identify as a member of a racial or ethnic minority community per self-report
Exclusion criteria 1. Uncontrolled psychosis, active suicidal ideation, psychiatric hospitalization within the past year 2. Cognitive impairment that prohibits participation in the study 3. Undergoing primary treatment for other cancer (i.e., advanced stage cancer) 4. Participating in a clinical trial involving AET 5. Diagnosis of Stage 0 (DCIS) breast cancer

Eligibility criteria (Table 1) will maximize homogeneity, reflect study focus, enhance rigor, and consider limitations. The intervention targets barriers to non-initiation of adjuvant endocrine therapy identified in women, as male patients face different challenges. While patients with metastatic cancer are also treated with endocrine therapy, there are different facilitators and barriers to initiation with incurable disease. Therefore, the focus on early-stage patients preserves the intervention scope.

Study staff will screen the EHR mentioning uncontrolled psychosis, suicidal ideation, psychiatric hospitalization within the past year, or cognitive impairment. If a note mentions any of the items in this criterion, study staff will refrain from approaching the patient. If this is not clearly documented in the EHR, the study staff will confer with the PI and/or discuss with the treating oncologist for further clarification and permission to approach.

We will aim to have at least 1/3 of the participants identifying as a racial or ethnic minority, in order to enroll a representative sample of experiences and concerns about AET to develop the culturally-informed intervention. With Spanish-speaking study staff, we will be able to enroll both English and Spanish-speaking participants. All materials have been translated and back-translated into Spanish with best practices for translation and quality control using Native Spanish speakers and an approved translation company, Linguistics Systems, Inc.

4.0 Research Subject Entry

4.1 Patient Recruitment, Pre-Screening, and Enrollment Procedures

Study staff will recruit BCS from the MGH Cancer Center and satellite sites MGH North Shore, MGH Waltham, MGH Cancer Center at Emerson Hospital, and MGH Cancer Center at Newton-Wellesley Hospital as well as the Dana-Farber Cancer Institute (DFCI) and satellite sites Milford, South Shore, Londonderry, Steward St. Elizabeth's Medical Center, Merrimack Valley, and Foxborough. While screening for our current study for adherence to AET, we identified at least 75 BCS at MGH main and satellite clinics that did not initiate AET as recommended. Therefore, we anticipate there will be sufficient potentially eligible patients to meet the accrual goal of up to 35 participants.

We will be enriching for participants of an ethnic or racial minority background. We will be doing this by reaching out directly to providers for referrals.

The following recruitment procedures will be executed by the lead site study staff, MGH Boston, for all MGH-affiliate study sites and DFCI sites. The three MGH-affiliate sites and all DFCI sites will not have any responsibilities regarding recruitment or enrollment. All study sites will be open through the DF/HCC IRB as the IRB of record.

We will complete a privacy waiver with our protocol submission to the Institutional Review Board (IRB) to allow study staff to screen the breast oncology clinic schedules and identify patients for study participation. We will also use this information to describe the enrolled sample.

Multiple recruitment methods detailed below have been strategically designed to ensure successful reach and engagement of this population while maintaining patient safety and research compliance:

- Proactive Electronic Health Record (EHR) Screening: Study staff will screen the breast cancer clinic schedules for demographic and clinical eligibility criteria to identify potentially eligible patients (under the use of a HIPAA waiver, submitted to the DF/HCC IRB). We will also use this information to describe the enrolled sample. Recommended AET start date will be determined from the progress note (e.g., patients prescribed AET prior to radiation are usually not expected to start until after radiation completion) and verified with the treating oncologist when necessary. If a patient is potentially eligible from EHR screening, study staff will request permission from the oncology clinician to approach patients. Specifically, study staff will email the cancer care team (i.e., oncologist, nurse practitioner) to inquire if they have any reservations about the study staff approaching the patient for study participation (Appendix 9.1). This email will also include an informative handout for clinicians to familiarize themselves with study aims and relevant procedures (Appendix 9.2).
- Rally Recruitment Portal: Study staff will submit a recruitment advertisement to the MGB Rally Recruitment Portal (Appendix 9.3, 9.4). Through this portal, interested and potentially eligible patients will be able to send their contact information to the study staff. The study staff will then preliminarily assess eligibility in the EHR, and study staff will reach out to interested patients, using the study screening and telephone scripts to assess fit and eligibility for the study (Appendices 9.5, 9.6).
- Provider and Self-Referral: Patients may be referred to contact study staff by receiving a study flyer (Appendices 9.11, 9.12), seeing a study flyer posted at MGH, or by hearing about the study from an oncology provider. Study staff will provide clinicians at other cancer institutions (e.g., Memorial Sloan Kettering Cancer Center, Moffitt Cancer Center, Sylvester Cancer Center (University of Miami), Tisch Cancer Institute (Mt. Sinai)) with recruitment materials (i.e., flyers) that can be shared with patients.
- Social Media Posts: Study staff can post study advertisements on social media outlets (Facebook, Instagram, Twitter, Reddit) for recruitment purposes. Suggested language and postings are found in Appendix 9.30.

For patients meeting initial eligibility criteria and with clinician permission to approach, trained study staff will approach the patient at a clinic visit or by telephone to initiate the informed consent discussion and explain the study procedures. The study staff will first introduce the study to patients and ask if they have started taking their AET. If the patient indicates that they are not interested in the study, or are currently taking AET, study staff will collect the reason for refusal for the purposes of documentation and future study reporting. Depending on their reasons for refusal, study staff may request permission to re-approach some patients in the future, such as for later phases of this study.

For patients who engage via social media or are at other cancer institutions, they will self-report their age, diagnosis/staging, hormone receptor status, and ECOG score. We will aim to maximize recruitment of participants of a racial/ethnic minority via this method.

If the patient indicates that they are interested in the study and have not started taking their AET, the study staff

will screen the potentially eligible patient. Patients will be eligible if they have been recommended AET and have not started taking it within three weeks of the proposed start date, or if they are recommended to start AET in the future (e.g., post-radiation completion) and they have significant hesitancies about starting AET. Hesitancy to start AET will be indicated by a score of >/=4 on the question, "how hesitant are you to start AET?" with 0 = not at all hesitant, and 10 = extremely hesitant. Once eligibility has been confirmed, the study staff will initiate the informed consent process verbally (if approached by telephone) or in-person (if approached in-clinic).

4.2 The Informed Consent Process

We will follow the DF/HCC Policy CON-100: Informed Consent Process to obtain and document informed consent. Study staff can review the study details, offer study participation, and obtain informed consent in-person or verbally. Both the written and the verbal consent forms describe all study procedures, information about potential risks and benefits of participation, and information regarding who they can contact for further questions. The forms also state that participation is voluntary, that participants can refuse to answer any questions, that they can withdraw from the study at any time, and that study participation is in no way related to their medical care. Study participants who do not provide consent will be asked the reason why they prefer to not participate in the study.

- Verbal Consent Process: We are requesting an alteration of HIPAA to allow for a waiver of Written Documentation of Consent. This study meets the requirements for a waiver as it is a Minimal Risk study, and all study procedures can be communicated verbally. This Waiver will allow study staff to recruit participants remotely to address barriers to study enrollment including infrequent in-person visits, lack of space in clinic, and patients' time constraints. Verbal consent allows for greater flexibility while assuring patient safety in response to changing healthcare practices. Study staff will contact potential participants via telephone to guide them through verbal consent forms that describe all study procedures, information about potential risks and benefits of participation, and information regarding who they can contact for further questions. The participant will be given ample opportunity to ask questions and take their time to consider their participation. All patients who provide verbal consent will receive an unsigned copy of the written informed consent. The study staff may contact eligible patients to obtain verbal consent using the HIPAA-compliant verbal consent form. If the patient does not answer the phone study staff may leave a voicemail (Appendix 9.7, 9.8).
- Spanish-speaking Consent Process: Patients who speak Spanish will have all study procedures and information regarding risks, benefits and study contacts explained to them via the use of an interpreter (in-person or remotely) or a Spanish-speaking study staff member with a witness present. Study staff will sign the English verbal consent form and document interpreter information when necessary.
- For all patients who provide consent, we will obtain HIPAA authorization. This may be done remotely through the REDCap platform by the patient typing their name and checking an assurance confirming that the typed name acts as an electronic signature or in person.

4.3 Registration

Participants who meet eligibility criteria and provide informed consent will be registered in the Clinical Trials Management System (CTMS) OnCore, as required by per DF/HCC SOP REGIST-101. Registration will occur once the participant has completed the baseline assessment. Study staff will complete the protocol-specific eligibility checklist, verifying that the participant meets all inclusion and exclusion criteria.

4.4 Participant Communication Methods

It is important to access and maintain contact with participants through communication methods they are most comfortable with, including phone, text, and email correspondence. During the informed consent process, study staff will elicit patient preferences about methods of study contact to facilitate participation (e.g., scheduling study intervention sessions, sending reminders, etc.). The limitations of each method will be described to them in detail by the research coordinator. Specifically, patients may opt to pursue communication with study staff via phone, text, or email correspondence. Phone and email communication have been successful strategies to communicate with patients in prior psychosocial studies, and email and SMS text templates intended for study use can be found in Appendices 9.17, 9.18, 9.19, 9.20.

SMS Messaging. Participants may elect to provide a personal mobile phone number and provide permission to receive SMS messages via an online service (GoogleVoice) regarding the study that the study staff will monitor. Before doing so, participants will be informed of the limitations of using GoogleVoice, particularly emphasizing that it is not HIPAA-compliant and thus does not offer protection over their personal health information. Additionally, participants will be informed that this phone number is not monitored regularly and should not be used for urgent or emergency purposes. Participants will be advised that, in the case of an emergency, they should contact their care team or emergency services. In the event participants still prefer the use of text messaging, study staff will send brief messages containing limited information regarding intervention session reminders. Participants will be provided with the number for SMS study-related communications. Study staff will follow the templates as outlined in Appendix 9.19 and 9.21 for SMS communication. Under the discretion of trained study staff and extenuating circumstances, study staff may stray from the following templates to address scheduling/reminder situations not covered by the message templates. Under no circumstances will study staff ever screen or discuss personal medical history, exchange personal health information, or other sensitive information via SMS message. If a participant introduces sensitive information, including but not limited to the examples just listed, into a SMS message conversation, the study staff member will direct the participant to call them to discuss it further over the phone.

- Send Secure Email. Participants will be provided with the Partners Privacy language regarding encrypted emails and given the opportunity to opt-out of Send Secure emails. In previous psychosocial studies, participants have articulated difficulties with accessing encrypted emails and prefer the option to opt-out of such method of encrypted communication.

5.0 Study Design and Methods

5.1 Design/Study Type

The present protocol proposes to examine the single-arm pilot trial to examine feasibility and acceptability of a patient-centered, evidence-based, culturally competent, tailored intervention to encourage breast cancer survivors who have not begun taking adjuvant endocrine therapy to initiate the medication, enriching for Black, Hispanic/Latina, and Asian American BCS. AET initiation will be measured by a self-report questionnaire. Participants will complete assessments at baseline (within 14 days of consent), 1-month, and 3-months post-baseline measuring beliefs about AET necessity, satisfaction with patient-physician communication, perceived social support and quality of life.

5.2 Selection of Instruments

Instrument/Measure	**Screening**	**Baseline (14-day window)**	**1-month follow-up (+/- 7 day)**	**3-month follow-up (+/- 7 day)**
Chart Review	X			
Screening Questions (AET initiation)	X			
Demographics		X		
AET Initiation Question		X	X	X
Functional Assessment of Chronic Illness Therapy-Treatment Satisfaction-Patient Satisfaction (FACIT-TS-PS)		X	X	X
Beliefs about Medicines Questionnaire – Adjuvant Endocrine Therapy (BMQ-AET)		X	X	X
Multidimensional Scale of Perceived Social Support (MSPSS)		X	X	X
Functional Assessment of Cancer Therapy-Breast (FACT-B)		X	X	X
Hospital Anxiety and Depression Scale (HADS)		X	X	X
Self-Efficacy for Managing Symptoms Questionnaire (Self-Efficacy for Symptoms)		X	X	X
Measure of Current Status – Part A (MOCS)		X	X	X
Client Satisfaction Questionnaire (CSQ)			X	

Screening:

EHR Factors: The following information will be collected from participant EHR: MGH Main vs Affiliate site vs DFCI sites, demographic information, breast cancer stage, treatment (e.g., surgery, chemotherapy, radiation), AET type, approximate recommended AET start date, and medical or psychological co-morbidities.

AET Initiation questions: A question will be administered asking patients whether they have started taking their daily AET (yes vs. no). Patients who have not yet started AET will be considered eligible for study participation. Patients will also be asked how hesitant they are about starting their recommended hormonal therapy medication on a scale of 0-10.

Outcome Measures:

Demographics Questionnaire: Participants will self-report their age, gender, race/ethnicity, marital status, education level, and relationship status.

AET Initiation Question: This one item instrument will ask patients: At different times throughout your participation this study, you may or may not be taking/have started taking your hormonal therapy. "At this time, are you currently taking your hormonal therapy (e.g., Tamoxifen, Anastrozole/Arimidex, Exemestane/Aromasin, Letrozole/Femara)?" Patients will self-report their initiation of endocrine therapy.

Functional Assessment of Chronic Illness Therapy-Treatment Satisfaction-Patient Satisfaction (FACIT-TS-PS):[33] This thirty-item questionnaire will be administered to patients to assess satisfaction with communication with clinicians and nurses and consists of items such as "Did you doctor show genuine concern for you?". Each item is measured on a Likert-type scale of 0 (No, not at all) to 3 (Yes, and as much as I wanted). Subscale scores are computed by summing each individual item, multiplying the sum by the number of items in the subscale and dividing by the number of items answered. Over 50% of items in a subscale must be completed to receive a valid score. Subscales include physician communication (0-36 score range), treatment staff communication (0-12), technical competence (0-9), nurse communication (0-9), and confidence and trust (0-12).

Beliefs about Medicines Questionnaire – Adjuvant Endocrine Therapy (BMQ-AET):[34] This 10-item questionnaire will be administered to assess the perceived need for AET versus concerns about side effects or other negative consequences (i.e., Necessity-Concerns framework). The BMQ-AET has been used in studies measuring endocrine therapy adherence. This study will use one of the two scales, which is computed measuring perceived need for medication and concerns about disruptive medication effects. Items are measured on a Likert-type scale of 1 (strongly agree) to 5 (strongly disagree). Total scores are calculated by finding the sum of subscales that range 10-50.

Multidimensional Scale of Perceived Social Support (MSPSS):[35,36] This 12-item questionnaire will be administered to patients to assess patients' perceived social support. The validated and reliable scale consists of items, such as "my family really tries to help me," and is measured on a 7-point Likert scale. The item is divided into 3 subscales: family, friends, and significant other and the range of the total scale is 1-7.

Functional Assessment of Cancer Therapy-Breast (FACT-B):[37] The FACT-B is a validated measure used to assess multidimensional quality of life in patients with breast cancer. The measure captures five domains: physical well-being, social/family well-being, emotional well-being, functional well-being, and additional concerns. Each item is answered on a Likert-type scale of 0 (not at all) to 5 (very much). Subscale scores are computed by summing each individual item, multiplying the sum by the number of items in the subscale and dividing by the number of items answered. Total FACT-B scores can range from 0-148.

Hospital Anxiety and Depression Scale (HADS):[38, 39] The HADS is a valid self-report measure for assessing anxiety and depressive symptoms among patients in non-psychiatric hospitals. The 14-item measure contains seven questions to assess depressive symptoms and seven questions to assess anxiety symptoms to distinguish between the two. Patients indicate how they have been feeling on average over the past week. Each item is answered on a scale of 1 to 4. The four possible answer choices vary and adjust for each question. Total subscale scores range from 0-21.

Self-Efficacy for Managing Symptoms Questionnaire (Self-Efficacy for Symptoms):[40] The Self-Efficacy for Symptoms Questionnaire is a modified version of the self-efficacy scale to assess patient self-efficacy in managing symptoms related to their endocrine therapy medication. The measure asks patients to rate their confidence on a scale of 1 (not at all confident) to 10 (very confident) in their ability to decrease or control the side effects of their medication. This is an 8-item scale, and total scores range from 1-10.

Measure of Current Status (MOCS):[41] The MOCS is a 13-item scale which measures patients' current self-perceived ability on several skills. Examples of targeted content areas are ability to relax, restructure maladaptive thoughts, and choose appropriate coping responses. Each of the 13 items is answered on a scale of 0 (I cannot do this at all) to 4 (I can do this extremely well).

Other demographic and treatment-related factors affecting initiation will be collected from the EHR and examined as covariates.

Intervention Acceptability:
Client Satisfaction Questionnaire (CSQ):[42] The CSQ is a 3-item, validated measure to assess satisfaction with services provided to the patient, and asks questions such as, "to what extent has our program met your needs?" Each item is answered on a scale of 1-4. This will be administered at the 1-month assessment to evaluate intervention participants only to examine intervention acceptability. The total score range is 3-12.

5.3 Description of Proposed Study Intervention

Our proposed intervention will be constructed within the aforementioned theoretical framework, using existing literature to incorporate strategies to reduce modifiable barriers to endocrine therapy initiation. Dr. Jacobs developed the intervention outline with expertise from co-investigators Drs. Jennifer Temel and Dr. Beverly Moy who are experts in cancer outcomes research and breast oncology and health equity, respectively. The data gathered from the semi-structured interviews has informed the intervention and be instrumental in refining it to optimize patient-centeredness.

The nurse-led intervention will be a brief, two-session, culturally competent, evidence-based intervention via videoconferencing software administered by a breast oncology nurse practitioner. The sessions will begin once baseline assessments and enrollment are complete, and the sessions will be approximately 2 weeks apart. Both sessions will aim to take place prior to the planned and agreed upon AET start date per the treatment plan with their oncology team. Study staff will work with patients on a case-by-case basis to schedule the sessions in a timeline that aligns with their treatment plan. Patients have the option to request attending these sessions via phone or in person.

The intervention and study materials will be translated into Spanish and delivered by nurse practitioner, Kathryn Post, PhD, in either English or Spanish. An interpreter will be present either in person or remotely for the intervention for patients who speak Spanish only. Both sessions will take place within one month of the baseline assessment. The intervention will target known modifiable barriers to AET initiation, including support and communication with clinicians, perceived therapeutic efficacy of AET, and managing expectations of symptoms and side effects, but will be primarily driven by barriers identified by the patient. Therefore, the session will begin by probing and identifying the individual and culture-specific barriers to initiation in multiple domains. The interventionist and patient will then problem-solve barriers to initiation through motivational interviewing, cognitive-behavioral techniques, and medication education. The intervention is informed by the Health Belief Model (HBM), the Cognitive Model of Adjustment to Cancer, and Motivational Interviewing Techniques. First, the intervention will address perceived risk and medication efficacy in line with the HBM, which maintains that the health behavior (i.e., initiating AET) will be adopted if the patient perceives (a) risk for a condition, (b) that the medication will reduce risk, (c) that benefits outweigh costs, and (d) self-efficacy for taking medication. Second, driven by the Cognitive Model of Adjustment to Cancer, the intervention will include strategies for enhancing coping with side effects, reframing cognitive self-talk about AET efficacy, and identifying and enhancing social support. CBT is effective in helping patients manage concerns, fears, and actual cancer-related side effects. Finally, Motivational Interviewing techniques will help the patient explore and resolve ambivalence with attention to their readiness for change. Sessions will be audio-recorded and at least 10% will be reviewed for treatment fidelity. Intervention acceptability will be evaluated using the CSQ.

5.4 Data Collection and Provisions to Protect the Privacy Interests of Subjects

Participants will be given the option to complete the above instruments either on paper, over a secure REDCap portal or over the telephone. Study staff will send assessments to participants at the start of their timepoint window and will follow-up periodically throughout to ensure receipt and completion of assessments. Assessments that are completed on paper will be entered into the secure REDCap database by study staff.

Patients will receive an Intervention Manual which has been informed by the Qualitative Phase of this study (21-331) (Appendix 9.25).

Patients will additionally receive a copy of the Intervention Manual and a welcome letter with study expectations (Appendix 9.21, 9.22), and a study timeline document (Appendix 9.23, 9.24). As detailed in the Data Safety Monitoring Plan (Section 6.0), all subjects will receive a confidential number identifier. All participants will be identified on study assessments by their number identifier.

Identifiers, such as name, will only be used during the initial data retrieval process and can be destroyed once all data records have been obtained and data analysis has been completed as discussed previously.

5.5 Description of Study Process

After completing the baseline assessment and enrollment, we will schedule the patient's intervention sessions. Sessions will take place via videoconferencing software (Zoom). If a patient prefers, these sessions can also be held in person or over the phone. Each session will last approximately 60 minutes. Participants will be reminded that they can decline to discuss any topic that is presented during the sessions. Interventionists will complete a post-session survey following each session (Appendix 9.26). 80% of sessions will be audio-recorded and at least 10% randomly selected, stratified by interventionist, and reviewed with study staff for treatment fidelity. Content fidelity will be assessed by calculating the percentage of key intervention topics addressed out of total topics, with a goal of 90%. Feedback will be given to interventionists to enhance adherence to the protocol.

The nurse-led intervention will be administered by trained study staff (under direct supervision and guidance from the PI) and study sessions will be conducted in English or Spanish using an intervention manual. This manual will be finalized after the completion of Phase I of this study with input from Dr. Jennifer Temel, Dr. Beverly Moy, and Kathryn Post, PhD. Following the intervention, we will offer participants optional semi-structured interviews to gather feedback on the sessions (Appendix 9.27). We will then modify the intervention iteratively to reflect participants' feedback in order to best address the needs of patients who have not started or are hesitant to initiate their AET medication. The study materials, including consent forms, recruitment materials, patient-facing materials and study measures, not otherwise available in Spanish from their licensor, will be translated (forwards and backwards) into Spanish by Linguistic Systems, Inc and Spanish-speaking investigators and coordinators in our Cancer Outcomes Research and Education Program (CORE). This group has extensive experience providing translation services for researchers at Harvard Medical School and Beth Israel Deaconess Medical Center. After the translation, a second linguist will edit the Spanish-language materials for quality assurance, following best practices in the translation industry.

Special Concerns

We do not anticipate any major complications with this study. To reduce burden, participants will be offered the opportunity to complete the intervention sessions via Partners approved videoconferencing software (Zoom). If a patient prefers, these sessions can also be held in person or over the phone. If a participant expresses distress during the study sessions, they will be reassured that they can stop the session and they are not required to respond to any topics presented during the sessions which they find upsetting. They will also be reminded that study participation is voluntary. If a participant remains distressed, the principal investigator, a psychologist, will offer a referral to supportive care services in the Psychiatric Oncology Service in the MGH Cancer Center, and assess safety prior to terminating the intervention session.

Participants may experience some discomfort talking about some of the topics brought up during the sessions or answering study assessment questions; however, they may choose not to discuss topics or answer questions that are distressing. Participants may also experience some discomfort being audio recorded, for the purposes of qualitative data collection. Confidentiality will be detailed on the consent form and discussed in detail so that participants are fully informed of their right to request information and to withdraw from the study at any time without impacting their care. We will also discuss the importance of maintaining confidentiality at the beginning of each session.

Breach of confidentiality is a concern in all studies with human subjects. Patient participants will be completing individual intervention sessions that will be audio-recorded; thus, safeguards will be put in place to ensure that participant information is kept private and confidential. Participants' data will be kept on Lab Archives, a Mass General Brigham electronic secure research lab notebook, and Business Dropbox, a cloud-based storage that is compliant with Mass General Brigham's policies and procedures. Data stored on Lab Archives and Dropbox

will only be accessible to the Principal Investigator and IRB-approved study staff. Data will not be shared with individuals other than study staff and any identifiable information about study participants will be destroyed after all data analyses are complete.

Compensation

Participants will not endure any additional costs as part of their participation in this research study. As such, we do not anticipate any financial burden on study participants. The study intervention visits will not be billed.

We will remunerate participants $10 for each assessment packet completed for up to $30 total.

Handling of Study Documents

Study source documents, including but not limited to signed informed consent forms, completed eligibility checklists, and participant questionnaires, will be scanned and stored digitally as certified copies on a secure drive only available for access to trained study staff working with the documents. The drive will be only accessible with proper invitation to the drive by the Principal Investigator through their Partners account, which will require personal username and password information to access. Trained study staff will follow specific standard operating procedures for handling source documents and certifying each copy appropriately. The procedures are as follows. After source documentation is filled out by the participant, study staff will collect the original source document. The study staff member scanning documents will be kept as consistent as possible throughout the duration of the study to ensure uniformity among source documentation handling. Location, time, and date of the scanning of the document will be recorded at the time of scanning. Study staff will fill out the Source Documentation Certified Copy Cover Sheet (Appendix 9.29) and include this as the first page of the electronic version of the source document. After the source document is scanned and the corresponding electronic document is confirmed to be legible, all facing the correct direction, and together as a single document, it will be collected and destroyed immediately. Study staff will destroy the original copy of the source document by following MGH procedures of destroying documents with Personal Health Information (PHI). Electronic versions of source documents will allow study staff to access these documents regardless of where the original copy is stored, which may be inconvenient, increase study staff burden, and study cost if storage of documents is far from the location where research activities will be conducted or required to be placed in long term storage. This process has been developed streamlined, and successfully implemented in DF/HCC Protocol #18-603.

5.6 Adverse Reactions and Their Management

Reporting Adverse of Unanticipated Events

We do not anticipate any harm with our study procedures. While some topics probed in study assessments and the intervention may be sensitive in nature, our study staff has extensive experience conducting social behavioral intervention on sensitive topics without any adverse events. No adverse or unanticipated events occurred in previous studies of psychological interventions conducted by our research group. Reportable adverse events would include a breach of confidentiality. Should adverse or unanticipated events occur during the study, a trained study staff member will report the events to the IRB as soon as they are discovered.

Anticipated Reactions

As Phase 2 of this study consists of a 2-session, in-person or virtual intervention with 3 study surveys, there are no ingested medications and no biomedical procedures. It is unlikely that participants will be at any risk for physical harm because of study participation. Participants may find some of the questions to be emotionally upsetting, and if so, they may experience some distress.

Reaction Management

A detailed consent form will be signed by study staff after the participant provides consent, following the explanation by study staff. The consent form will include all study procedures, information about potential risks and benefits of participation, and information regarding whom the participant can contact for further questions. It will also state that participation is voluntary, that participants can refuse to answer any questions, that they can withdraw from the study at any time, and that study participation is in no way related to their medical care. All study staff will complete the required human subjects training before they can work on any human subject aspects of the study.

If a participant expresses distress during the psychological intervention visits, they will be reassured by the clinician or study staff member conducting the intervention session that they can stop at any time and that they do not need to continue participating in content or discuss any intervention topics/questions which they find upsetting. They will also be reminded that study participation is voluntary. If participants remain distressed, they will be offered an opportunity to meet with a psychologist in the Psychiatric Oncology Service at the MGH Cancer Center to help address their distress.

For all participant assessments given throughout the study, study staff will review assessments upon receipt from participants for completion and to assess distress. On the HADS, patients who endorse ≥11 on even items for a more severe range for depression will be called by qualified study staff (e.g., Dr. Jacobs, a licensed clinical psychologist, as well as trained clinical psychology practicum fellows). If a participant completes the distress assessment online through the secure REDCap portal, a study staff member will check the responses and notify the PI for follow-up if needed within 72 hours of receipt. If a participant completes assessments on paper, study staff will check the responses and notify the PI for follow-up if needed within 72 hours of receipt. If a participant completes assessments over the phone, study staff will notify the PI for follow-up if needed within 72 hours of receipt. If the patient needs further outpatient services for depression, including pharmacotherapy, or is at risk for self-harm requiring hospitalization, study staff will make the necessary referrals for treatment. For example, for patients who are distressed but in no danger to self or others, study staff will refer either to the MGH Oncology Social Work Service or to the MGH Outpatient Psychiatry Department (617-724-5600), including the Cognitive-Behavioral Therapy Program. If suicidality or risk of harm to others is otherwise discovered at any study visit, the participant will be referred to appropriate services. Specifically, in the case that hospitalization is required, study staff will contact and escort the patient to the MGH Acute Psychiatry Service (617-726-2995), with the aid of the MGH Police & Security if necessary (617-726-2121). If a referral for outpatient services is made, or the patient requires escort to the MGH Acute Psychiatry Service, study staff will notify the health care team, including the primary oncologist.

The PI and trained study staff will meet weekly to review study progress, ensure properly implementation of the intervention, and review any adverse reactions that occur. The PI and the research assistant will review consents and collected data to ensure proper adherence to study protocol.

6.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Data and Safety Monitoring Plan

The purpose of the data and safety monitoring plan is to establish standards that will ensure that this protocol complies with Federal Regulations, Health Insurance Portability and Accountability Act (HIPAA) requirements, and applicable Dana-Farber Harvard Cancer Center (DF/HCC) Standard Operating Procedures.

General Approach: We have developed a comprehensive data and safety monitoring plan for the proposed project. Throughout the award period, weekly meetings will take place with the research team: Jennifer Temel, MD and Beverly Moy, MD, MPH, and study staff. Specifically, meetings will include ongoing review of study protocol, assessment procedures, and issues

related to recruitment, data collection, and management. Study staff will also discuss any human subject issues that arise.

General Roles and Responsibilities: We will use several coordinated strategies to monitor study recruitment, enrollment, and retention, as described in the following table. We will also closely track collection of patient-reported assessments, as these measures are an essential aspect of our study procedures and outcomes. For all strategies identified in the table, we will develop study tracking forms that will be reviewed at the weekly team meetings. Study tracking forms will be used to create a record of all decisions made and actions taken. I will send a report ahead of the meeting detailing study progress and setting the agenda. The following monitoring and reporting steps will be taken for each study activity:

Study Activity	Monitoring and Reporting Mechanism
Recruitment	• The designated CRC will generate a weekly report outlining the number of patients approached and reasons for ineligibility or disinterest in study participation.
Informed Consent	• The CRC will generate a weekly report detailing the number of participants who consented to the study. • The PI will go through any issues related to informed consent with the CRC weekly or earlier if urgent.
Enrollment	• The CRC will generate a weekly enrollment report.
Assessments	• The CRC will conduct a review for completeness and accurate data entry. • The CRC will maintain participant records of distress levels at each timepoint and follow Reaction Management if required.
Intervention	• The CRC will contact patients to test the videoconferencing technology. • The PI and trained study staff will review at least 10% of audio-recorded treatment sessions. • The CRC will maintain a record of participant progress in sessions, including attendance.
Retention	• The CRC will generate a weekly report detailing completion of follow-up assessments and retention strategies implemented for each participant. • The CRC will generate a weekly report of all participants who withdraw from study.
Analysis	• The PI will work closely with study biostatistician, Nora Horick (scientific advisor in biostatistics), on all qualitative and quantitative analyses.

Specific PI Roles and Responsibilities

I will be responsible for all aspects of conducting the protocol; I will:

- Oversee the coordination, development, submission, and approval of the protocol to the DF/HCC as well as subsequent amendments.
- Ensure that the investigators and study staff are qualified and appropriately resourced to conduct the protocol.
- Carry out a Data and Safety Monitoring Plan as detailed in this document.
- Ensure that each participating study staff member receives adequate protocol training prior to enrolling participants and throughout the trial's conduct as needed.
- Monitor progress and overall conduct of the study.
- Conduct review of 10% of intervention sessions for process and content fidelity.
- Conduct weekly supervision for clinical protocol interventionists.
- Review data and maintain timely submission of data for study analysis.

- Ensure compliance with all requirements as set forth in the Code of Federal Regulations, DF/HCC, HIPAA requirements, and the approved protocol.
- Commit to provisions that the protocol will not be rewritten or modified by anyone other than the overall PI.
- Monitor accrual and address concerns if accrual goals are not met.

The Massachusetts General Hospital Cancer Center is expected to comply with all applicable federal regulations and requirements, the protocol and HIPAA requirements. Specifically, it will:

- Oversee the data collection process.
- Maintain documentation of Serious Adverse Events (SAE) reports and deviations/violations.
- Maintain regulatory documents which include but are not limited to the following: IRB approvals/notifications, confirmation of Federal wide Assurances (FWAs), all SAE submissions, screening logs, and IRB approved consents.
- Conduct regular communications with the PI and maintain documentation of relevant communications.
- Document the delegation of research specific activities to study personnel.
- Maintain regulatory files.
- Have office space, office equipment, and internet access that meet HIPAA standards.
- Participate in quality assurance activities and meet with monitors or auditors at the conclusion of a visit to review findings.
- Promptly provide follow-up and/or corrective action plans for any monitoring queries or audit findings.

Informed Consent Requirements. The DF/HCC approved informed consent document will serve as a template for the informed consent.

Protocol Confidentiality. All documents, investigative reports, or information relating to the participants are strictly confidential. Confidentiality is assured as participants will be identified on all study materials only by participant number, visit number, and date of visit. By recording the study data in this manner, the information can be considered 'de-identified,' and therefore compliant with the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") of HIPAA. Participants' data will be kept in a computer file that is password protected and this password will be changed whenever the staff changes. This password-protected file will be stored on the encrypted MGH network drive on hospital computers. Only the Principal Investigator and study staff will have access to the data. We will keep a link between participant number and participant's name in a separate file, also password protected (with a different password).

Data Management Organizational Structure Data. Study forms will undergo a systematic and rigorous editing process prior to being keyed into the database. The research assistant will routinely evaluate the data and discuss any problems and questions with the study staff, myself, and mentors at the regular weekly team meetings. Data management formal reports on record status across the three following domains will be employed: entered, verified, and edited. These reports of data records will be evaluated once a month during the final team meeting of the month. All study data (including data from the Electronic Health Record) will be stored on the encrypted MGH network drive on hospital computers and will be password protected. To ensure data protection, backup copies automatically generated by MGH computer systems will be available.

Data Safety and Monitoring Plan. The following procedures will be followed, in compliance with NIH requirements, to ensure the safety of study participants and the validity and integrity of data:

Data Repository: The MGH Cancer Outcomes Research Program (CORE) has coordinated research initiatives over the past ten years that have established procedures and technologies for data collection and management. I will oversee all aspects of data collection for the study and the research assistant will have the operational responsibility of data management. We will develop a study specific data management protocol and standard operating procedures for the creation and testing of all study forms, data collection, quality control, and data extraction. These forms will be standardized. We will provide ongoing oversight of data management

throughout the study, and will be responsible for generating reports and datasets for quality control and data analysis. All data management activities will utilize REDCap, a HIPAA-secure, web-based survey application for electronic collection and management of research and clinical trial data. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the study staff with planning assistance from Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS) group. REDCap provides an intuitive interface for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. Data management reports will be generated weekly and discussed during the study staff meetings.

- Serious Adverse Events: Expedited review will occur for all events meeting the Food and Drug Administration (FDA) definition of a SAE (i.e., any fatal event, immediately life-threatening event, permanently or substantially disabling event, event requiring or prolonging inpatient hospitalization, Unanticipated Problems [UPs], or any congenital anomaly). This also includes any event that a study investigator judges to impose a significant hazard, contraindication, side effect, or precaution. For purposes of this study, all SAEs will be required to be reported to the PI, the DF/HCC IRB, and federal agencies (National Cancer Institute, FDA, and the NIH Office of Biotechnology Activities), regardless of any judgment of their relatedness to the study. All relevant information will be reported to the study investigators for each SAE including information about the event and its outcome, study condition, concomitant medications, the subject's medical history and current conditions, and all relevant laboratory data. Notification by secure e-mail of all related study forms shall be made to the DF/HCC IRB within 24 hours of the occurrence of any SAE. Information will be reviewed and a determination made of whether there was any possible relevance to the study interventions. Reporting to NIH will be made according to their respective regulations governing SAE reporting.
- Non-Serious Adverse Events: At weekly meetings, the study staff will discuss summaries of the numbers and rates of adverse events by treatment group. These reports will include types of events, severity, and treatment phase.
- Other Safety-Related Reports: At weekly meetings, the study staff will discuss summary reports of treatment retention and reasons for dropout or withdrawal by treatment group.
- Study Stopping Rules: We do not have a pre-specified stopping rule given the low-risk nature of the proposed study. However, if at any point the DF/HCC or the study investigators judge that the risks of study procedures outweighs the benefits, the project will be stopped immediately.
- Procedures to ensure confidentiality, preparation of reports, minutes, and recommendations: We will work with the CRC to prepare study reports and circulate them to the study staff during the weekly scheduled project meetings. These reports will include overall study progress and safety data. At the conclusion of each research group meeting, the investigators will determine whether any changes in the conduct of the trial are recommended.

7.0 Statistical Analyses

7.1 Primary and Secondary Endpoints

Our primary endpoint of this phase of feasibility and acceptability will be measured by rates of enrollment (>50%), participant retention (70%), intervention attendance (>70% attending at least 1 of 2 sessions), and intervention satisfaction (>75% reporting satisfaction greater than the CSQ's midpoint).

Our secondary aim is to assess intervention-related changes in primary and secondary outcomes at one- and three- months post-baseline. We will explore changes in satisfaction with patient-physician communication, perceived social support, self-efficacy for symptom management, and quality of life.

7.2 Sample Size

To determine feasibility in a single-arm pilot trial (up to N=35), estimate effect size, and finalize the intervention and study protocol to apply for an NIH grant to conduct a full-scale efficacy trial.

7.3 Early Stopping Rules

Study participation will be terminated at any time upon the participant's request.

7.4 Definition of Allowance in Design for Unevaluable/Ineligible Participants

Not applicable.

7.5 Analysis Plan

Aim 1: Feasibility and acceptability will be measured by rates of enrollment (>50%), participant retention (>70%), intervention attendance (>70% attending at least 1 of 2 sessions), and intervention satisfaction (>75% reporting average satisfaction greater than the CSQ's midpoint).

Aim 2: First, data will be analyzed with the intention-to-treat principle and assessed for statistical assumptions and patterns of missingness, implementing Multiple Imputation with maximum likelihood if appropriate. Sample size justification. We may over-accrue to ensure that a total of up to 45 BCS complete the study. This pilot study will provide a preliminary estimate of the rate of AET initiation within one month from baseline. With up to 30 participants, the width of the exact 95% confidence interval (CI) for the rate of AET initiation at one month will be at most 37.4% (i.e., +/- 18.7%). If at least 24% of participants initiate AET within one month, the study will rule out a post-intervention initiation rate of lower than 10% based on the lower limit of the exact 95% CI. We will conduct exploratory analyses to examine whether participants' baseline characteristics are associated with AET initiation at one month using Fisher's exact tests and unpaired t-tests. For secondary outcomes, we will conduct paired samples t-tests to assess intervention-related changes in satisfaction with communication with clinicians and treatment, Necessity-Concerns Framework, perceived support, self-efficacy for managing side effects, and QOL from baseline to one-month post-baseline. In addition, we will use linear mixed effects regression models to evaluate the change in secondary outcomes across all three assessment time points. We will interpret 95% Confidence Intervals and Cohen's d effect sizes (D=[(Mean 1)–(Mean 2)]/pooled Standard Deviation), with magnitudes of 0.3, 0.5, and 0.8 for small, medium, and large effects, respectively. We will conduct sensitivity analyses to examine whether changes in outcomes are differ among racial and ethnic groups.

Participants will be given the opportunity to receive a summary of study results at the completion of the study. If a request is made, the study staff will provide the participant with an abstract of the study at the end of data collection and analysis.

7.6 Handling of Missing Data in the Analysis

The analyses for this study will focus on study completers to estimate the effect of the 2-session, patient centered intervention. The primary endpoint will be based on acceptability and feasibility aspects of the study. We will use the intention-to-treat principle for analyses with all participants. After we examine patterns of missingness, we will use maximum likelihood with multiple imputation to account for missing data.

8.0 References

1. Burstein HJ, Lacchetti C, Griggs JJ. Adjuvant Endocrine Therapy for Women With Hormone Receptor-Positive Breast Cancer: ASCO Clinical Practice Guideline Focused Update. *J Oncol Pract*. 2018;15(2):106-7. Epub 2018/12/05. doi: 10.1200/JOP.18.00617. PubMed PMID: 30523754.
2. Davies C, Godwin J, Gray R, Clarke M, Cutter D, Darby S, et al. Relevance of breast cancer hormone receptors and other factors to the efficacy of adjuvant tamoxifen: patient-level meta-analysis of randomised trials. *Lancet*. 2011;378(9793):771-84. doi: 10.1016/S0140-6736(11)60993-8. PubMed PMID: 21802721; PubMed Central PMCID: PMC3163848.
3. Neugut AI, Hillyer GC, Kushi LH, Lamerato L, Leoce N, Nathanson SD, et al. Non-initiation of adjuvant hormonal therapy in women with hormone receptor-positive breast cancer: The Breast Cancer Quality of Care Study (BQUAL). *Breast cancer research and treatment*. 2012;134(1):419-28.
4. Demissie S, Silliman RA, Lash TL. Adjuvant tamoxifen: predictors of use, side effects, and discontinuation in older women. *J Clin Oncol*. 2001;19(2):322-8. PubMed PMID: 11208822.
5. Pini T, Griggs J, Hamilton A, Katz S. Patterns and correlates of adjuvant breast cancer endocrine therapy use. *Journal of Clinical Oncology*. 2011;29(15_suppl):510-.
6. Kimmick G, Anderson R, Camacho F, Bhosle M, Hwang W, Balkrishnan R. Adjuvant hormonal therapy use among insured, low-income women with breast cancer. *Journal of Clinical Oncology*. 2009;27(21):3445.
7. Zavala VA, Bracci PM, Carethers JM, Carvajal-Carmona L, Coggins NB, Cruz-Correa MR, et al. Cancer health disparities in racial/ethnic minorities in the United States. *Br J Cancer*. 2021;124(2):315-32. Epub 2020/09/09. doi: 10.1038/s41416-020-01038-6. PubMed PMID: 32901135; PubMed Central PMCID: PMCPMC7852513.
8. Reeder-Hayes KE, Meyer AM, Dusetzina SB, Liu H, Wheeler SB. Racial disparities in initiation of adjuvant endocrine therapy of early breast cancer. *Breast Cancer Res Treat*. 2014;145(3):743-51. Epub 2014/05/01. doi: 10.1007/s10549-014-2957-z. PubMed PMID: 24789443; PubMed Central PMCID: PMCPMC5499377.
9. Livaudais JC, Hershman DL, Habel L, Kushi L, Gomez SL, Li CI, et al. Racial/ethnic differences in initiation of adjuvant hormonal therapy among women with hormone receptor-positive breast cancer. *Breast Cancer Res Treat*. 2012;131(2):607-17. Epub 2011/09/16. doi: 10.1007/s10549-011-1762-1. PubMed PMID: 21922245; PubMed Central PMCID: PMCPMC3375495.
10. Emerson, MA, Achacoso, NS, Benefield HC, Troester MA, Habel LA. Initiation and adherence to adjuvant endocrine therapy among urban, insured American Indian/Alaska Native breast cancer survivors. *Cancer*. 2021;127(11): 1847-1856. PMID: 33620753.
11. Makubate B, Donnan PT, Dewar JA, Thompson AM, McCowan C. Cohort study of adherence to adjuvant endocrine therapy, breast cancer recurrence and mortality. *Br J Cancer*. 2013;108(7):1515-24. doi: 10.1038/bjc.2013.116. PubMed PMID: 23519057; PubMed Central PMCID: PMCPMC3629427.
12. Sabate E, De Geest S. Adherence to long-term therapies management: a call for cardiovascular nursing managers and policymakers. *Prog Cardiovasc Nurs*. 2004;19(1):28-9. PubMed PMID: 15017153.
13. Kroenke C, Hershman DL, Adams S, Kwan ML, Kushi LH. Social support at diagnosis and noninitiation, discontinuation, and nonadherence to adjuvant hormonal therapy in the Pathways Study. American Society of Clinical Oncology; 2017.
14. Shelton RC, Clarke Hillyer G, Hershman DL, Leoce N, Bovbjerg DH, Mandelblatt JS, et al. Interpersonal influences and attitudes about adjuvant therapy treatment decisions among non-metastatic breast cancer patients: an examination of differences by age and race/ethnicity in the BQUAL study. *Breast Cancer Res Treat*. 2013;137(3):817-28. Epub 2012/12/22. doi: 10.1007/s10549-012-2370-4. PubMed PMID: 23263696; PubMed Central PMCID: PMCPMC3563273.
15. Liu Y, Malin JL, Diamant AL, Thind A, Maly RC. Adherence to adjuvant hormone therapy in low-income women with breast cancer: the role of provider-patient communication. *Breast Cancer Res Treat*. 2013;137(3):829-36. doi: 10.1007/s10549-012-2387-8. PubMed PMID: 23263740; PubMed Central PMCID: PMC3553239.

16. Friese CR, Pini TM, Li Y, Abrahamse PH, Graff JJ, Hamilton AS, et al. Adjuvant endocrine therapy initiation and persistence in a diverse sample of patients with breast cancer. *Breast Cancer Res Treat*. 2013;138(3):931-9. doi: 10.1007/s10549-013-2499-9. PubMed PMID: 23542957; PubMed Central PMCID: PMC3633703.
17. Heiney SP, Parker PD, Felder TM, Adams SA, Omofuma OO, Hulett JM. A systematic review of interventions to improve adherence to endocrine therapy. *Breast Cancer Res Treat*. 2019;173(3):499-510. Epub 2018/11/01. doi: 10.1007/s10549-018-5012-7. PubMed PMID: 30387003.
18. Fisher TL, Burnet DL, Huang ES, Chin MH, Cagney KA. Cultural leverage: interventions using culture to narrow racial disparities in health care. *Med Care Res Rev*. 2007;64(5 Suppl):243S-82S. doi: 10.1177/1077558707305414. PubMed PMID: 17881628; PubMed Central PMCID: PMCPMC2505343.
19. Finitsis DJ, Vose BA, Mahalak JG, Salner AL. Interventions to promote adherence to Endocrine Therapy among breast cancer survivors: A meta-analysis. *Psycho-Oncology*. 2018.
20. Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med*. 2005;353(5):487-97. doi: 10.1056/NEJMra050100. PubMed PMID: 16079372.
21. Siminoff LA, Ravdin P, Colabianchi N, Sturm CMS. Doctor-patient communication patterns in breast cancer adjuvant therapy discussions. *Health expectations*. 2000;3(1):26-36.
22. Mott-Coles S. Patients' cultural beliefs in patient-provider communication with African American women and Latinas diagnosed with breast cancer. *Clin J Oncol Nurs*. 2014;18(4):443-8. doi: 10.1188/14.CJON.443-448. PubMed PMID: 25095298.
23. Jacobs JM, Pensak NA, Sporn NJ, MacDonald JJ, Lennes IT, Safren SA, et al. Treatment Satisfaction and Adherence to Oral Chemotherapy in Patients With Cancer. *J Oncol Pract*. 2017:JOP2016019729. Epub 2017/04/11. doi: 10.1200/JOP.2016.019729. PubMed PMID: 28398843.
24. Bluethmann SM, Murphy CC, Tiro JA, Mollica MA, Vernon SW, Bartholomew LK, editors. Deconstructing decisions to initiate, maintain, or discontinue adjuvant endocrine therapy in breast cancer survivors: a mixed-methods study. Oncology nursing forum; 2017: NIH Public Access.
25. Heisig SR, Shedden-Mora MC, von Blanckenburg P, Schuricht F, Rief W, Albert US, et al. Informing women with breast cancer about endocrine therapy: effects on knowledge and adherence. *Psychooncology*. 2015;24(2):130-7. doi: 10.1002/pon.3611. PubMed PMID: 24953538.
26. Pan Y, Heisig SR, von Blanckenburg P, Albert U-S, Hadji P, Rief W, et al. Facilitating adherence to endocrine therapy in breast cancer: stability and predictive power of treatment expectations in a 2-year prospective study. *Breast cancer research and treatment*. 2018;168(3):667-77.
27. Golden SD, Earp JA. Social ecological approaches to individuals and their contexts: twenty years of health education & behavior health promotion interventions. *Health Educ Behav*. 2012;39(3):364-72. Epub 2012/01/20. doi: 10.1177/1090198111418634. PubMed PMID: 22267868.
28. Jacobs JM, Walsh EA, Rapoport CS, Antoni MH, Park ER, Post K, et al. Development and Refinement of a Telehealth Intervention for Symptom Management, Distress, and Adherence to Adjuvant Endocrine Therapy after Breast Cancer. J Clin Psychol Med Settings. 2020. Epub 2020/11/21. doi: 10.1007/s10880-020-09750-4. PubMed PMID: 33219901.
29. Jacobs JM, Ream ME, Pensak N, Nisotel LE, Fishbein JN, MacDonald JJ, et al. Patient experiences with oral chemotherapy: Adherence, symptom, and quality of life. J Natl Compr Canc Netw. In Press/Forthcoming.
30. Greer JA, Amoyal N, Nisotel L, Fishbein JN, MacDonald J, Stagl J, et al. A systematic review of adherence to oral antineoplastic therapies. Oncologist. 2016;21(3):354-76. doi: 10.1634/theoncologist.2015-0405. PubMed PMID: 26921292.
31. Stagl JM, Lechner SC, Carver CS, Bouchard LC, Gudenkauf LM, Jutagir DR, et al. A randomized controlled trial of cognitive-behavioral stress management in breast cancer: survival and recurrence at 11-year follow-up. Breast Cancer Res Treat. 2015;154(2):319-28. doi: 10.1007/s10549-015-3626-6. PubMed PMID: 26518021.
32. Stagl JM, Bouchard LC, Lechner SC, Blomberg BB, Gudenkauf LM, Jutagir DR, et al. Long-term psychological benefits of cognitive-behavioral stress management for women with breast cancer: 11-

year follow-up of a randomized controlled trial. Cancer. 2015;121(11):1873-81. doi: 10.1002/cncr.29076. PubMed PMID: 25809235; PubMed Central PMCID: PMC4441540.
33. Peipert JD, Beaumont JL, Bode R, Cella D, Garcia SF, Hahn EA. Development and validation of the functional assessment of chronic illness therapy treatment satisfaction (FACIT TS) measures. Qual Life Res. 2014 Apr;23(3):815-24. doi: 10.1007/s11136-013-0520-8. Epub 2013 Sep 24. PMID: 24062239.
34. Brett J, Hulbert-Williams NJ, Fenlon D, Boulton M, Walter FM, Donnelly P, Lavery B, Morgan A, Morris C, Horne R, Watson E. Psychometric properties of the Beliefs about Medicine Questionnaire-adjuvant endocrine therapy (BMQ-AET) for women taking AETs following early-stage breast cancer. *Health Psychol Open*. 2017 Nov 17;4(2):2055102917740469. doi: 10.1177/2055102917740469. PMID: 29379627; PMCID: PMC5779943.
35. Zimet GD, Powell SS, Farley GK, Werkman S, Berkoff KA. Psychometric characteristics of the Multidimensional Scale of Perceived Social Support. *J Pers Assess.* 1990 Winter;55(3-4):610-7. doi: 10.1080/00223891.1990.9674095. PMID: 2280326.
36. Calderón, C., Asensio-Martínez, E., Ferreira, E., Manzano-Fernández, A., Rogado, J., Antoñanzas-Basa, M., Palacín-Lois, M., Fernández-Montes, A., Gómez-Sánchez, D., Lorenzo-Seva, U., Ferrando, P. J., & Jiménez-Fonseca, P. (2021). Escala Multidimensional de Apoyo Social Percibido (MSPSS) en pacientes con cáncer: propiedades psicométricas e invariancia de medida. *Psicothema*, *33*(Número 1), 131-138. Recuperado a partir de https://reunido.uniovi.es/index.php/PST/article/view/17080
37. Gray LA, Wailoo AJ, Hernandez Alava M. Mapping the FACT-B Instrument to EQ-5D-3L in Patients with Breast Cancer Using Adjusted Limited Dependent Variable Mixture Models versus Response Mapping. *Value Health*. 2018 Dec;21(12):1399-1405. doi: 10.1016/j.jval.2018.06.006. Epub 2018 Aug 9. PMID: 30502783; PMCID: PMC6288064.
38. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand.* 1983 Jun;67(6):361-70. doi: 10.1111/j.1600-0447.1983.tb09716.x. PMID: 6880820.
39. De Las Cuevas Castresana C, Garcia-Estrada Perez A, Gonzalez De Rivera Jl. "Hospital Anxiety and Depression Scale" y Psicopatología Afectiva. *Anales De Psiquiatría.* 1995, 126-130.
40. Shelby RA, Edmond SN, Wren AA, Keefe FJ, Peppercorn JM, Marcom PK, Blackwell KL, Kimmick GG. Self-efficacy for coping with symptoms moderates the relationship between physical symptoms and well-being in breast cancer survivors taking adjuvant endocrine therapy. *Support Care Cancer.* 2014 Oct;22(10):2851-9. doi: 10.1007/s00520-014-2269-1. Epub 2014 May 13. PMID: 24821365.
41. Antoni, M. H., Lechner, S. C., Kazi, A., Wimberly, S. R., Sifre, T., Urcuyo, K. R., Phillips, K., Gluck, S., & Carver, C. S. (2006). How stress management improves quality of life after treatment for breast cancer. *Journal of Consulting and Clinical Psychology, 74,* 1143-1152.
42. Attkisson CC, Zwick R. The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. Eval Program Plann. 1982;5(3):233-7. doi: 10.1016/0149-7189(82)90074-x. PMID: 10259963.

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9.1 Suggested Clinician Email Template: Request to Approach

Addressing Non-Initiation of Recommended Adjuvant Endocrine Therapy for Patients with a Culturally Informed Intervention
PI: Jamie Jacobs, Ph.D.

Dear [Dr./NP/PA PROVIDER NAME],

I am a research coordinator working with Dr. Jamie Jacobs on a study to promote the initiation of endocrine therapy with a virtual, 2-session, culturally informed intervention for breast cancer survivors. Participants must be fluent in English or Spanish.

Your patient(s) may be eligible for the study:

Name	MRN	DOB

I would like to approach her regarding the study. Please let me know at your earliest convenience if I should refrain from approaching this patient for any reason. If I do not hear from you, I will follow-up in person to request permission.

Study participation does not preclude you and the rest of the patient's care team from medically treating the patient's symptoms per your clinical judgment.

Please feel free to let me know if you have any questions or concerns. Additionally, I have included a brief attachment with more study information.

Thank you,
[name of study staff]

[name of study staff]
Clinical Research Coordinator
Massachusetts General Hospital
[study staff email]
[study phone number]

9.2 Clinician Handout

Addressing Non-Initiation of Recommended Adjuvant Endocrine Therapy for Patients with a Culturally Informed Intervention

Study Rationale

- Up to 30% of BCS do not initiate AET as recommended.
- BCS of a racial or ethnic minority are disproportionately less likely to initiate AET.
- AET initiation is a modifiable health behavior with established predictors, with some being more salient for minority BCS.
- Interventions to improve initiation to AET are needed and should be culturally sensitive.
- Based on a qualitative study, we developed a culturally competent, two-session, nurse-led intervention to promote AET initiation in a diverse sample of early-stage, hormone receptor-positive BCS who have delayed initiation or have hesitations about initiating.

Study Specifics

- This is a single-arm pilot study in which up to 35 patients will be recruited to participate in a two-session intervention with purposeful recruitment of racial/ethnic minorities.
- We will aim to have one-third of the participants identifying as a racial or ethnic minority, in order to enroll a representative sample of experiences and concerns.
- The intervention consists of 2, one-hour sessions delivered over videoconferencing with a nurse practitioner. If necessary, these sessions can be delivered in person or via phone.
- All patients will be asked to complete assessments at baseline, 1-month, and 3-months after enrollment.

What Is Needed from You as the Clinician?

- Approve or deny study staff request to approach potentially eligible participants
- Refer patients you think may be eligible and a good fit for the study
- Provide care as usual

Patient Inclusion and Exclusion Criteria

- Female, age 21 or older, ability to read and respond in English or Spanish
- Diagnosis of early-stage (Stage I-IIIB), hormone-receptor positive breast cancer
- Recommended to start AET at least 3 weeks prior and not currently taking AET OR recommended to start AET in the future and reports hesitations to start AET as determined by a score of >/= 4 (range =0-10) when asked "How hesitant are you about starting your recommended hormonal therapy? (0=Not at all hesitant and 10 = Extremely hesitant)"
- Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
- Does not have Stage 0 (DCIS) breast cancer
- May not have psychiatric or cognitive impairment
- May not have a psychiatric hospitalization within the past year
- Is not currently undergoing primary treatment for other cancer (i.e., advanced stage cancer)
- Is not participating in a clinical trial involving AET

Study Contact Information:

- Please send potentially eligible patients to the study coordinator [name and email] or to the study PI, Dr. Jamie Jacobs, at jjacobs@mgh.harvard.edu.

9.3 Rally Recruitment Portal Advertisement

Headline: Addressing Non-Initiation of Recommended Hormonal Therapy for Patients with a Culturally Informed Intervention

Summary: If you were diagnosed with breast cancer and have not yet begun taking a hormonal therapy, you may be eligible to participate in this research study. Participants will complete a brief, 2-session, culturally informed intervention.

Project Title: Addressing Non-Initiation of Recommended Hormonal Therapy for Patients with a Culturally Informed Intervention

Categories: Breast Cancer, Cancer, Medicines

Project Image:

Funding Source: Electronic Space Systems Corporation

Institutions conducting research: Massachusetts General Hospital, Dana-Farber Cancer Institute

IRB Organization: DF/HCC Dana Farber Cancer Institute

Recruitment start date: TBD
Recruitment end date: 5/1/2023

What are you studying?
We are studying a tailored, patient centered, culturally informed intervention for women who have not yet started taking hormonal therapy for breast cancer. This program will address challenges and barriers of beginning hormonal therapy.

Why is it important?
Patients diagnosed with breast cancer can experience a variety of challenges and barriers around beginning hormonal therapy. This program will allow women to explore and manage their specific concerns around starting these medications with a cancer center clinician.

9.4 Rally Recruitment Portal Advertisement - Spanish

Titular: Enfrentando a la Falta de Iniciación de Tratamiento Hormonal que es Recomendado a Pacientes, con una Intervención Fundamentada por la Cultura

Resumen: Si usted una sobriviente con cáncer de mama y aun no ha comenzado tratamiento hormonal, puede ser elegible para participar en este estudio de investigación. Los participantes completarán una breve intervención de 2 sesiones, culturalmente informada.

Titulo del Proyecto: Enfrentando a la Falta de Iniciación de Tratamiento Hormonal que es Recomendado a Pacientes, con una Intervención Fundamentada por la Cultura

Clasificaciones: Cáncer de Mama, cáncer, Medicinas

Imagen del Proyecto:

Fuente de Fondos: Electronic Space Systems Corporation

Instituciones Conduciendo el Estudio: Massachusetts General Hospital, Dana-Farber Cancer Institute

Organización del IRB: DF/HCC Dana Farber Cancer Institute

Reclutamiento Empieza: TBD
Reclutamiento Termina: 5/1/2023

¿Qué están investigando?
Estamos investigando la viabilidad y eficacia de una intervención adaptada, centrada en el paciente y culturalmente informada para mujeres que aún no han comenzado a tomar tratamiento hormonal para el cáncer de mama o tienen reservaciones sobre empezarlo. Este programa abordará los desafíos y las barreras de comenzar el tratamiento hormonal.

¿Cuál es la importancia?
Sobrevivientes del cáncer de mama pueden enfrentar una variedad de desafíos y barreras al comenzar el tratamiento hormonal. Este programa les permitirá a estas mujeres explorar y enfrentar sus preocupaciones específicas sobre el inicio de estos medicamentos con una clínica del centro oncológico.

9.5 Suggested Recruitment and Eligibility Phone Script

Hi, this is [Study Staff Name] calling from Massachusetts General Hospital/Dana-Farber Cancer Institute. Is this [Patient Name]?

A1. Self-referral call-back: Thank you for reaching out to our study team regarding the study. I would be happy to give you a brief overview of the study if you have a few minutes. Is now a good time?

IF YES: Continue to Section B.

IF NO: Is there a better time in the coming days I could give you a call back? [Continue to Section E.]

A2. Recruitment call: I am calling regarding a research study you might be eligible for that your oncologist, [provider name], thought you might be interested in. Is this a good time I could give you a brief overview of the study?

IF YES: Continue to Section B.

If NO: Continue to Section E.

B. Study Description

This is a study about starting hormonal therapy, a type of medication that your oncologist recommended you take for breast cancer. This program consists of 2 sessions with a nurse over Zoom, to address any challenges or concerns you may be experiencing around beginning this medication. These visits would take place over a secure videoconferencing software Zoom. Does this sound like something you might be interested in?

IF YES: Continue to Section C.

IF NO: Continue to Section E.

C. Eligibility Pre-Screening

Thanks for your interest. To determine whether this study is a good fit for you, I am wondering, have you started taking the hormonal therapy prescribed to you by your oncologist?

IF YES: Continue to Section E.

IF NO: Continue in Section C.

On a scale of 0-10, with 0 indicating that you aren't at all hesitant and 10 indicating that you are extremely hesitant, how hesitant are you about starting your hormonal therapy?

IF >/=4: Continue in Section D.

IF <4: Continue to Section E.

D. Consent Form Access and the Informed Consent Discussion

The next step is for us to go through the verbal consent process over the phone and I will send you a copy over email for your records.

IF YES: [Proceed to complete the verbal consent process]

IF NO: Okay, we can also complete the informed consent process through the mail. I will send you two copies of the consent form through the mail for you to sign both and send one back to me using a prepaid envelope I'll include. Additionally, I'll include the screening measures to verify your eligibility. [Collect address and continue to Section E]

E. Not Interested, Refusal, Paper-Consent Preference, Ineligible Outcome

Thank you so much for your time today. Please feel free reach out with any questions or concerns related to the study.

9.6 Suggested Recruitment and Eligibility Phone Script - Spanish

Hola, mi nombre es [Study Staff Name] estoy llamando por parte de Massachusetts General Hospital/Dana-Farber Cancer Institute. Es usted [Patient Name]?

A1. Llamada de Autorreferencia: Muchas gracias por contactar a nuestro equipo sobre nuestro estudio. Si tiene algunos minutos, me encantaría darle un resumen corto sobre nuestro estudio. ¿Está disponible?

SI DICE "Sí": Continúe a la Sección B.

SI DICE "No": ¿Tendría algún momento en los próximos días en el pueda contactarme otra vez con usted? [Continúe a la Sección E.]

A2. Llamada de Reclutamiento: Estoy llamando sobre un estudio en el puede ser elegible para participar, y que su oncólogo, [provider name], pensó que a lo mejor le pudiera interesar. Si tiene algunos minutos, me encantaría darle un resumen corto sobre nuestro estudio. ¿Está disponible?

SI DICE "Sí": Continúe a la Sección B.

SI DICE "No": Continúe a la Sección E.

B. Descripción del Estudio

Este estudio esta relacionado con el comienzo del tratamiento hormonal, un tipo medicación que su oncólogo le ha recomendado que tome para cáncer de mama. Este programa incluye 2 sesiones con una enfermera a través de Zoom, individuales y culturalmente informadas para enfrentar cualquier desafío o preocupaciones que pueda estar teniendo al comenzar a tomar este medicamento. Estas visitas se realizarían a través de un software de videoconferencia segua utilizando Zoom. ¿Le interesaría participar?

SI DICE "Sí": Continúe a la Sección C.

SI DICE "No": Continúe a la Sección E.

C. Preselección de Elegibilidad

Muchas gracias por su interés. ¿Para determinar si este estudio es una buena opción para usted, le quería preguntar si usted ha empezado a tomar el medicamento de tratamiento hormonal que le prescribió su oncólogo?

SI DICE "Sí": Continúe a la Sección E.

SI DICE "No": Continúe a la Sección C.

En una escala del cero al diez, cero indicando que no tiene duda en absoluto y diez indicando que está sumamente indecisa ¿Qué tan indecisa está usted de comenzar su tratamiento hormonal?

Si ≥4: Continúe a la Sección D.

Si <4: Continúe a la Sección E.

D. Acceso al Formulario de Consentimiento y Discusión Sobre el Consentimiento Informado

El próximo paso es de que revisemos el formulario de consentimiento y le enviaré una copia por correo electrónico para sus registros.

SI DICE "Sí": Continúe en la Sección D. [Proceed to complete the verbal consent process]

SI DICE "No": No hay problema, también se puede completar este proceso por el correo. Le mandare dos copias del formulario por el correo para que usted firme las dos y me mande una copia devuelta usando un sobre prepagado que también le enviare. Adicionalmente, incluiré los requisitos de selección para verificar su elegibilidad. [Obtener su Dirección y Continúe a la Sección E]

E. Ningún Interés, Rechazo, Prefiere Copia del Consentimiento en Papel, No es elegible.
Muchísimas gracias por su tiempo. Si usted tiene alguna preocupación o pregunta acerca del estudio, por favor no dude en contactarnos.

9.7 Suggested Recruitment Voicemail Script

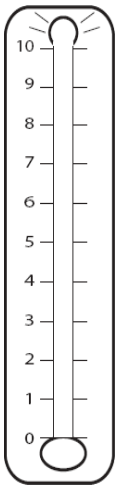
Hi, this is [study staff contact] calling from Massachusetts General Hospital/ Dana-Farber Cancer Institute. I am calling to get in contact with [patient name] about a program you may be interested in. Please give me a call back when you have the chance. You may reach me at [study staff contact information]. Thank you.

9.8 Suggested Recruitment Voicemail Script - Spanish

Hola, me llamo [study staff contact] estoy llamando por parte de Massachusetts General Hospital/ Dana-Farber Cancer Institute, para contactar a [patient name] sobre una oportunidad que le podría interesar. Por favor devuélvame la llamada cuando tenga tiempo. Me puede contactar al [study staff contact information]. Muchas gracias.

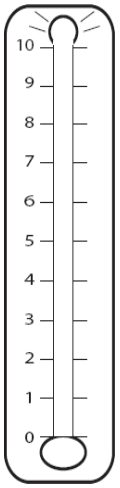
9.9 Patient Screening Question

How hesitant are you about starting your recommended hormonal therapy?
(0=Not at all hesitant, 10=Extremely hesitant)



9.10 Patient Screening Question - Spanish

¿Qué tan indecisa está usted acerca de comenzar su tratamiento hormonal recomendado? (0=Para nada indecisa, 10=Sumamente indecisa)



Mass General Brigham
Mass General Cancer Center

Initiate

Barriers to beginning hormonal therapy after breast cancer

The Mass General Cancer Outcomes Research Program is conducting a research study to support women who are given hormonal therapy after breast cancer treatment.

If you:

- Are at least 21 years old
- Have hesitations or worries about starting hormonal therapy
- Have not yet started taking medication such as Tamoxifen, Arimidex, Letrozole, Exemestane.

You may be eligible to participate in a two-session virtual intervention program to discuss and problem solve challenges to beginning hormonal therapy.

If you would like to learn more about this research study, please tell your oncologist or contact the study coordinator, **[study staff name],** at **[study staff phone]** or at **[study staff email].**

CORe | Cancer Outcomes Research

9.12 Recruitment Flyer – Spanish

Mass General Brigham
Mass General Cancer Center

Initiate

Comenzar el Tratamiento Hormonal después de Cáncer de Mama.

El Programa de MGH Cancer Outcomes Research esta conduciendo un estudio para apoyar a mujeres puestas en tratamiento hormonal después de recibir tratamiento para cáncer de mama.

Si usted:

- Tiene 21 o mas años
- Tiene dudas sobre comenzar su trataiento hormonal
- No ha empezado a tomar medicamentos como Tamoxifen, Arimidex, Letrozole, Exemestane.

Puede ser eligible para participar en un programa de intervención virtual con dos sesiones para discutir y resolver desafíos relacionados con el comienzo del tratamiento hormonal.

Si quiere aprender mas sobre este estudio, por favor dígale a su oncólogo o contacte a la coordinador(a) del estudio [study staff name], al [study staff phone] o por [study staff email].

CORe Cancer Outcomes Research

9.13 Suggested Email Template for Sending a Copy of the Verbal Consent and HIPAA Authorization

Subject line: “INITIATE Study at MGH/DFCI”

Hello [participant name],

Thank you for your participation in the INITIATE study. Please see attached a copy of the consent form for your records. If you have any questions or concerns, please do not hesitate to reach out.

Thanks!

[Study staff name]

[Study Staff Contact Information]

Suggested Electronic HIPAA Authorization Email Template

Subject line: “INITIATE Study HIPAA Authorization”

Hi [participant name],

Thank you for participating in our research study! To allow study staff to access health information, I’ve included a link to the HIPAA authorization form. All information is kept confidential for only trained study staff and will be stored securely.

Thanks,
[Study Staff Name]

[Study Staff Contact Information]

[REDCap-generated link]

9.14 Suggested Email Template for Sending a Copy of the Verbal Consent and HIPAA Authorization - Spanish

Subject line: “El estudio INITIATE en MGH/DFCI”

Saludos [participant name],

Le agradecemos por su interés en nuestro nuevo estudio conducido en Massachusetts General Hospital. Por favor consulte adjunta una copia del formulario de consentimiento para sus registros. Por favor, no dude en contactarnos si usted tiene alguna pregunta o preocupación.

Gracias,
[Study Staff Name]

[Study Staff Contact Information]

Suggested Electronic HIPAA Authorization Email Template - Spanish

Subject line: “El estudio INITIATE HIPAA Autorización”

Saludos [participant name],

Le agradecemos por su participacion en nuestro studio. Para permitir que el personal del estudio acceda a la información de salud, he incluido un enlace al formulario de autorización de HIPAA. Toda la información se mantiene confidencial solo para el personal capacitado del estudio y se almacenará de forma segura.

Gracias,
[Study Staff Name]

[Study Staff Contact Information]

[REDCap-generated link]

9.15 Participant Locator Form– English

1. Participant Name
2. Mailing Address
3. Preferred phone number
    - Mobile
    - Home
    - Work
    - Other
4. Phone number
5. Can study staff leave voicemails regarding your participation in the study?
    - Yes
    - No
6. If you would like to receive SMS text messaging reminders, please check the box below
    - I give permission to the INITIATE study team to contact me regarding this research study, using the mobile phone number provided.
    - I understand that any communication using SMS with the study team is NOT HIPAA-compliant, not encrypted, and does not guarantee confidentiality.
    - I understand that this number is not monitored regularly and should not be used for urgent or emergency situations.
        - Yes, I understand and give my permission for the INITIATE study to SMS message me.
        - No, I do not give my permission.
7. Best e-mail address to reach you at
8. Preferred survey delivery method
    - Email
    - Via hard-copy mail
9. The Partners HealthCare standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners HealthCare.

    If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by encrypted email despite this risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research group/study only.

    Would you prefer to receive encrypted or unencrypted emails from the study team?
    - Encrypted
    - Unencrypted

9.16 Participant Locator Form– Spanish

1. Nombre de participante
2. Dirección de envoi
3. Teléfono preferido para contactarle:
    - Celular
    - Casa
    - Trabajo
    - Otro
4. Número del teléfono
5. ¿Podemos dejar mensajes con respeto a su participación del estudio?
    - Sí
    - No
6. Si quiere recibir mensajes de SMS como recordatorio, por favor selecciona la opción adecuada:
    - Le doy permiso al equipo de estudio, INITIATE, contactarme al número de teléfono proveído con respeto al estudio
    - Yo entiendo que el equipo de estudio, INITIATE, no garantiza la confidencialidad: cualquier comunicación usando SMS con el equipo de estudio no cumple con el HIPPA y no está encriptado
    - Yo entiendo que este número de teléfono no está monitoreado con frecuencia y no debe ser usado en situaciones urgentes o de emergencia
        i. Sí, yo entiendo las condiciones y le doy permiso al equipo de estudio, INITIATE, contactarme a través de mensajes de SMS.
        ii. No, no quiero darte permiso.

7. El mejor correo electrónico para contactarla/o:

8. Método preferido de entrega para una encuesta
    - Correo electrónico
    - Copia impresa por el correo

9. El estándar de Partners HealthCare es enviar corroes electrónicos de forma segura. Para asegurar nuestro estándar, requerimos que usted cree su propia cuenta con una contraseña segura. Usted puede usar esta contraseña para acceder correos electrónicos seguros de Partners HealthCare.

    Si prefiere, nosotros podemos enviar correos electrónicos inseguros que no son encriptados. Si elige usar corroes electrónicos que no son encriptados es posible que resulte en el uso desautorizado y la diseminación de tu información. Si quiere correr el riesgo de usar correos electrónicos inseguros, Partners HealthCare no asumirá responsabilidad. Su preferencia de recibir correos electrónicos inseguros aplicará solo a correos electrónicos entre usted y el equipo de estudio.
    ¿Preferiría recibir correos electrónicos del equipo de estudio encriptados o no encriptados?
    - Encriptados
    - No encriptados

9.17 Suggested Participant Email Reminder Templates

Email Reminder Templates

[The following templates will be used for emailing depending on context and status of a participant through the protocol. Under the discretion of trained study staff and extenuating circumstances, study staff may stray from the following templates to address scheduling/reminder situations not covered by the following. Under no circumstances will study staff ever screen or discuss personal medical history, exchange personal health information, or other sensitive information via email. If a participant introduces sensitive information, including but not limited to the examples just listed, into an email, the study staff member will direct the participant to call them to discuss it further over the phone.]

Intervention session reminder:

Hello _____,
We are reaching out regarding the INITIATE study at MGH/DFCI. This is a reminder that you have an INITIATE session tomorrow at _____. Please sign on to the session using the Telehealth link sent to you over email. Please contact [study staff contact] if you have any questions.
Thank you,
[Study Staff Member]

Questionnaire reminder:

Hello _____,
We are reaching out regarding the INITIATE study at MGH/DFCI. This is a reminder that it is time to complete the [1-month/3-month] questionnaire, which will take roughly 20 minutes. You have received the questionnaire via [email/mail]. Please contact [study staff contact] if you have any questions.
Thank you,
[Study Staff Member]

9.18 Suggested Participant Email Reminder Templates - Spanish

Recordatorio de la sesión de intervención:
Hola _____,
Nos estamos comunicando con respecto al estudio INITIATE en MGH/DFCI. Este es un recordatorio de que tiene una sesión de INITIATE mañana a las _____. Ingrese a la sesión utilizando el enlace de telesalud que se le envió por correo electrónico. Comuníquese con [study staff contact] si tiene alguna pregunta.

Gracias,
[Study Staff Member]

Recordatorio de cuestionario:
Hola _____,
Nos estamos comunicando con respecto al estudio INITIATE en MGH/DFCI. Este es un recordatorio de que es hora de completar el cuestionario del (Primer mes/Tercer mes) [1-mes/3-mes], que durara unos 20 minutos. Usted ha recibido el cuestionario por [correo electrónico / correo]. Comuníquese con [study staff contact] si tiene alguna pregunta.

Gracias,
[Study Staff Member]

9.19 Suggested Participant SMS Text Reminder Templates

Text Message Reminder Templates

[The following templates will be used for SMS messaging depending on context and status of a participant through the protocol. Under the discretion of trained study staff and extenuating circumstances, study staff may deviate slightly from the following templates to address scheduling/reminder situations not covered by the following. Under no circumstances will study staff ever screen or discuss personal medical history, exchange personal health information, or other sensitive information via SMS message. If a participant introduces sensitive information, including but not limited to the examples just listed, into a SMS message conversation, the study staff member will direct the participant to call them to discuss it further over the phone.]

Intervention reminder:
Hello _____, this is a message from the INITIATE study at MGH/DFCI. This is a reminder that you have an INITIATE session tomorrow at ____. Please sign on to the session using the Telehealth link sent to you over email. Please contact [study staff contact] if you have any questions. Thank you.

Questionnaire reminder:
Hello _____, this is a message from the INITIATE study at MGH/DFCI. This is a reminder that it is time to complete the [1-month/3-month] questionnaire. You have received the questionnaire via [email/mail]. Please contact [study staff contact] if you have any questions.

Thank you.
[Study Staff Member]

9.20 Suggested Participant SMS Text Reminder Templates - Spanish

Recordatorio de intervención:
Hola, este es un mensaje del estudio INITIATE en MGH/DFCI. Este es un recordatorio de que tiene una sesión de INITIATE mañana a las _____. Ingrese a la sesión utilizando el enlace de telesalud que se le envió por correo electrónico. Comuníquese con [study staff contact] si tiene alguna pregunta.

Gracias,
[Study Staff Member]

Recordatorio de cuestionario:
Hola _____,
Nos estamos comunicando con respecto al estudio INITIATE en MGH/DFCI. Este es un recordatorio de que es hora de completar el cuestionario del (Primer mes/Tercer mes) [1-mes/3-mes]. Comuníquese con [study staff contact] si tiene alguna pregunta.

Gracias,
[Study Staff Member]

9.21 INITIATE Welcome Letter – English

The INITIATE Study
Massachusetts General Hospital
Dana-Farber Cancer Institute
55 Fruit Street
Yawkey Center, Suite 10B
Boston, MA 02114
(617) 643-1777

[patient name]
[patient address]
[patient address]

Dear [patient name],

Please find your INITIATE workbook enclosed here for your upcoming first session.

As a reminder, you are scheduled for your INITIATE sessions [session 1 date at time] and [session 2 date at time].

Please feel free to contact [study staff name] at [study staff email] or [study staff phone]. Alternatively, you can also contact the principal investigator of the study, Dr. Jamie Jacobs, at jjacobs@mgh.harvard.edu or at 617-643-1777 with any related questions.

Thank you so much for your participation in the INITIATE study and we look forward to having you in the program!

Sincerely,

Jamie Jacobs, Ph.D. Leticia Varella, M.D. [study staff name]

MASSACHUSETTS GENERAL HOSPITAL CANCER CENTER

HARVARD MEDICAL SCHOOL

9.22 INITIATE Welcome Letter – Spanish

The INITIATE Study
Massachusetts General Hospital
Dana-Farber Cancer Institute
55 Fruit Street
Yawkey Center, Suite 10B
Boston, MA 02114
(617) 643-1777

[patient name]
[patient address]
[patient address]

Estimado/a [patient name],

Por favor Encuentre su libro de trabajo INITIATE incluido aquí para su primera sesión.

Como recordatorio, usted está programado para sus sesiones INITIATE el [session 1 date at time] y [session 2 date at time].

Por favor siéntase libre de contactar [study staff name] al [study staff email] o [study staff phone]. Alternativamente, también puede comunicarse con la investigadora principal del estudio, Dra. Jamie Jacobs, a jjacobs@mgh.harvard.edu o al 617-643-1777 con cualquier pregunta relacionada.

¡Muchas gracias por su participación en el estudio INITIATE y esperamos contar con su participación en el programa!

Sinceramente,

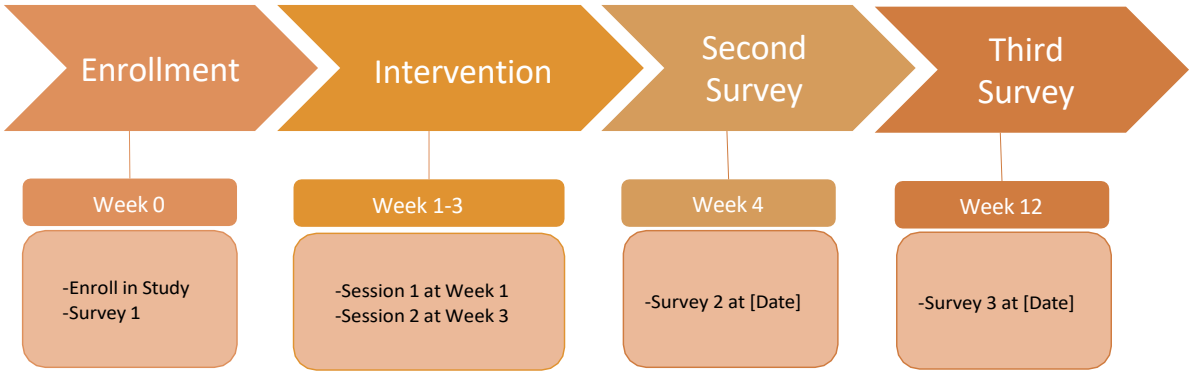
Jamie Jacobs, Ph.D. Leticia Varella, M.D. [study staff name]

MASSACHUSETTS GENERAL HOSPITAL CANCER CENTER

HARVARD MEDICAL SCHOOL

9.23 Participant Road Map

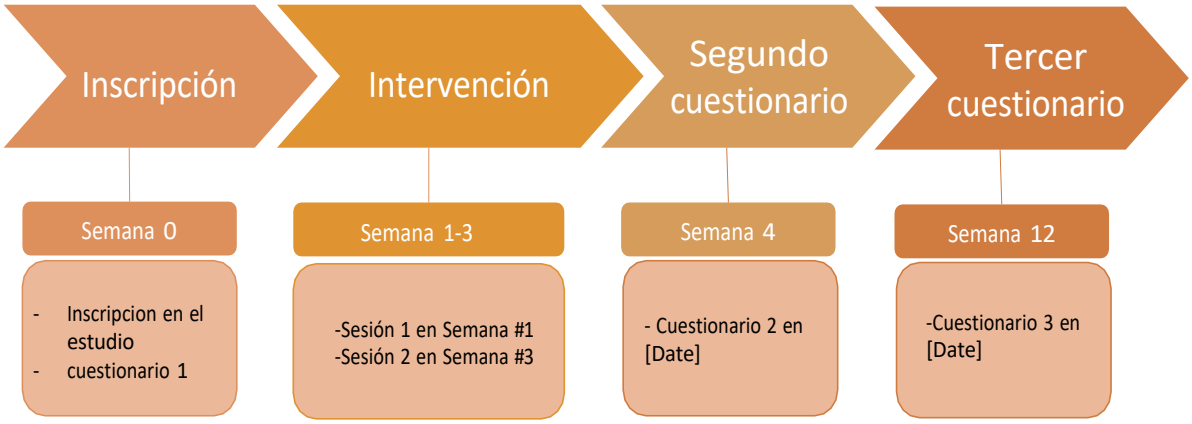
Welcome to the INITIATE Study! Here is a roadmap of what to expect as a participant in this study.



If you have any questions please contact [study coordinator names] at [study coordinator emails] or at [study phone number].

9.24 Participant Road Map - Spanish

¡Bienvenido al estudio INITIATE! Esto es lo que puede esperar como una participante en este estudio.



Si tiene alguna pregunta, comuniquese con [study coordinator names] en [study coordinator emails] o en [study phone number].

9.25 INITIATE Manual

[See separately attached appendix item; will be given to all participants.]

9.26 Interventionist Post-session Survey

INITIATE post-session survey

- Participant study ID
- Interventionist
- Date of session
- Session administered
- How long was the session approximately (in minutes)?
- Session Notes
    - Please note anything important about the session or scheduling
- Review of Homework Practice
    - Was the participant assigned homework for this session?
    - Please rate the patient's overall adherence to the homework:
        - 1. Did not complete
        - 2.
        - 3. Does some homework
        - 4.
        - 5. Satisfactory job
        - 6.
        - 7. Excellent compliance

9.27 Semi-structured Interview Guide

Introduction
Hello, my name is ___. You have been asked to participate in this interview to share your experiences going through the INITIATE program. I will ask you a variety of questions about your experiences during the study. I greatly appreciate your willingness to participate in this study.

This interview will take 15 minutes.

Everything that you share with me today is confidential, and your answers will not affect your future participation in studies or your access to medical services.

There are no right or wrong answers to these questions. It is very important for us to hear your thoughts and feelings on the program, so we can improve it for the future.

I would like to audio-record this interview because I will not be able to write all this information down. The interview will be transcribed word for word and will allow us to capture your thoughts and feelings in your own words. No identifying information, such as your name or names of others, will be included in the transcript. Additionally, your responses will never be reviewed individually. Responses will be collected and combined from all participants for feedback to the study team.

Do I have permission to record this interview?

Before we start, do you have any questions about what we are doing here today?

(START RECORDING)

1. How did you feel about the number of INITIATE sessions?
2. How did you feel about how long each session lasted?
3. How satisfied were you with the information you received?
4. Have you used any of the skills that you learned?
    - Probe: Relaxation skills, skills for coping with symptoms, etc.
5. How did you feel about the individual structure?
6. How did you feel about the videoconference?
7. How did you feel about the packet of questionnaires?
    - Probe: Too long?
    - Probe: Was anything confusing?
8. How did you feel about the number of times we asked you to complete the questionnaires?
9. Do you have any suggestions for how to improve our program?
10. Did anything get in the way of you being able to participate?
11. Would you recommend this to other women experiencing hesitation about starting hormonal therapy?

Questions related to cultural background:

- Can you share with me, how do you identify yourself (for example, as a Black Hispanic woman, as Chinese American)?

- Was there anything that got in the way of you participating in this study?

- Was there anything that got in your way of participating that relates to your race, ethnicity, culture, or other way you identify yourself?
    - Offer examples: were the questions in the survey relevant to you? were the examples in the workbook relevant to you (only for intervention participants)?

- What did you like about this study/program?

- What did you dislike about this study/program?

    - Is there anything related to your race, ethnicity, or cultural background that might get in the way of you taking your hormonal therapy medication every day?
        - Offer example: some groups might question how well these medications work, some may have less trust in their doctors and nurses.

    - Is there anything related to your race, ethnicity, or cultural background that might get in the way of your ability to manage side effects from the medication?
        - Offer example: some groups might question how well these medications work, some may have less trust in their doctors and nurses.

    - Do you feel you will be able to talk with your doctors and nurses about any questions you have had with your hormonal therapy?

    - Do you feel that your experience, or concerns about this medication, are the same or different from other women in a similar position?
    - Probe: how about women from different backgrounds?

- How do you think we could make this program meet the needs of women of different backgrounds?

- Is there anything you can think of, that could help support you to take the medication?

Remuneration Form

Remuneration for study participation.

Participant Name _____

Participant MRN _____

SSN or ITIN _____

Mailing Address _____

_____

_____

For study team:

☐ Baseline Assessment - $10 Date completed: _____

☐ 1-month Assessment - $10

☐ 3-month Assessment - $10 Date paid: _____

9.32 Source Documentation Certified Copy Cover Sheet

MASSACHUSETTS
GENERAL HOSPITAL

Cancer Outcomes Research Program (CORE)
Yawkey Building, Suite 10B
32 Fruit Street, Boston, MA 02114

Source Documentation – Certified Copy Cover Sheet

Type of Document: _____
Pages (including cover sheet): _____

This form serves to verify that the following scanned copy is of the exact original document, includes all pages, is legible, and confirms all wet-ink signatures.

Location Scanned: _____

Time & Date Scanned: _____

Scanned by:

_____ _____
Signature *Date*

_____ _____
Printed *Title*

9.33 Suggested Social Media posts (Facebook, Instagram, Twitter, Reddit)

Option 1: Have you been diagnosed with breast cancer and are you worried about starting your hormonal therapy (anastrozole, letrozole, tamoxifen)? If so, you may be eligible to participate in this research study at the Massachusetts General Hospital (MGH) Cancer Center.

We have created a culturally sensitive program to help you manage stress and worry about starting the medication. We are recruiting women of diverse racial and ethnic backgrounds (for example, Black, Latinx/Hispanic, Asian) who speak English and/or Spanish.

If enrolled, you will complete two 1-hour sessions over Zoom with a nurse practitioner from the MGH breast oncology department. You will be asked to complete 3 surveys over the course of the study and will be compensated for your time. Contact the study team to learn more at [contact information] [insert relevant hashtags]

Option 2: If you were diagnosed with breast cancer and have worries about taking your recommended hormonal therapy, you may be eligible to participate in this research study. Participants will complete a virtual, 2-session program with a nurse practitioner from the breast oncology department at Massachusetts General Hospital. If you are interested in participating, contact the study team at [contact information] [insert relevant hashtags]

Option 3: New #research at the Mass General Cancer Center and Dana-Faber Cancer Institute, led by clinical psychologist Dr. Jamie Jacobs, is offering a virtual program for women who have been recommended hormonal therapy after breast cancer treatment. If you are interested in participating, contact the study team at [contact information] [insert relevant hashtags]

Accompanied by flyer or logo.