# Trial in Progress: REJOIN Trial to Use Exercise and Education to Relieve Joint Pain in Older Breast Cancer Survivors Taking Aromatase Inhibitors

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## BACKGROUND

- Aromatase inhibitors (AI), a form of adjuvant hormonal therapy, is the standard of care for estrogen-receptor-positive (ER+) breast cancer survivors, most of whom are older than 65 years of age
- AIs have been demonstrated to significantly reduce recurrence and mortality risk, if taken as prescribed
- Arthralgia (joint pain) is a common side effect of AIs (affects up to 50% of users) and may degrade function and impede adherence. It is a common reason survivors stop hormonal therapy before the recommended duration of 5+ years
- Recent trials have shown that physical activity (PA) is underutilized yet effective for improving AI-induced arthralgia
- It has been suggested that providing education about AI symptom management strategies may contribute to better AI adherence
- Because older survivors are at high-risk of early discontinuation of hormonal therapy, addressing barriers to AI adherence, and empowering patients to negotiate these barriers, is a major priority in cancer survivorship care

## INNOVATION

**This research study is innovative because it:**

- Combines principles of exercise physiology with cancer-specific assessment
- Uses a transdisciplinary approach, integrating functional age in designing exercise interventions
- Informs refinements for future interventions specifically for older survivors
- Brings a clinical trial with a supportive care focus to an understudied population (older adults).

## RESEARCH QUESTION AND AIMS

**QUESTION:** Does a self-management approach (education + exercise) improve joint pain management better than standard of care?

- **Primary Aim:** Test the effect of a pilot intervention on arthralgia

*Hypothesis: Participants in the treatment group will report less pain than the control group.*

- **Secondary Aim:** Test the effect of a pilot intervention on adherence to aromatase inhibitors

*Hypothesis: Participants in the treatment group will report better AI Adherence than controls.*

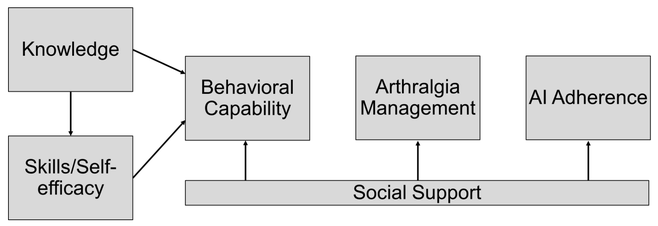



**Figure 1:** Conceptual model for a self-management intervention (derived from Social Cognitive Theory)

## METHODS

### STUDY DESIGN:

- Randomized controlled pilot trial
- All patients will attend a baseline visit prior to randomization, where they will receive ACS educational materials about hormonal therapy after breast cancer
- 1:1 randomization into treatment and control groups
- Treatment group receives eight weeks of bi-weekly supervised exercise sessions (60-minutes of low-impact aerobics and light weights) and 30 minutes of education about breast cancer survivorship (Figure 1) via **online video conferencing platform** followed by 8-weeks of at-home exercise, reinforced with phone counseling
- Follow-up visits occur at 4, 6, and 12 months post-randomization or initiation of exercise sessions (figure 2)

### ELIGIBILITY CRITERIA:

- 60 years of age or older
- ER+ non-metastatic breast cancer
- Newly diagnosed and completed chemotherapy/radiation
- Currently insufficiently active (i.e., less than 150 min or exercise per week or less than two strength training sessions per week)
- Started AIs within the last 6 months prior to randomization

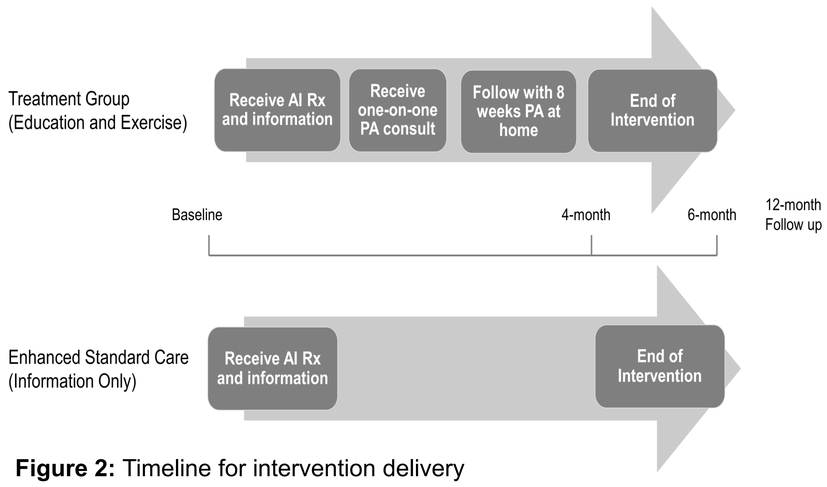



**Figure 2:** Timeline for intervention delivery

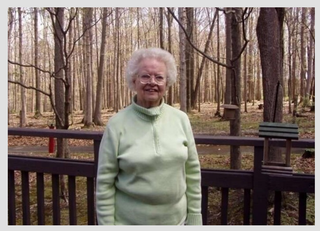
## PRELIMINARY RESULTS

- There are two sites involved in the REJOIN Study: Penn State College of Medicine and the Wake Forest University School of Medicine
- The accrual goal for the study is 24 patients, and there have been 13 patients enrolled between both sites (Table 1)
- Penn State College of Medicine consented 12 patients, and Wake Forest University School of Medicine has consented 1 patient so far
- Of the Penn State College of Medicine patients, six patients were randomized to the treatment group, and six were randomized to the control group. One patient from the control group and two patients from the treatment group withdrew
- In total, 10 enrolled patients completed all activities through the third assessment and 9 completed all study activities and provided assessments at four time points over one year. We had complete data from five from the control group and four from the treatment group
- Overall, we have had 75-83% retention from trial participants so far and **zero serious adverse events**, underscoring the safety and acceptability of the intervention

**Table 1:** Patient demographics for REJOIN recruitment to date

| | Patient Data |
|---|---|
| **Gender, n (%)** | Female: 13 (100%) |
| **Race, n (%)** | White: 13 (100%) |
| **Rural Status, n(%)** | From rural area: 6 (~50%) |
| **Ethnicity, n (%)** | Not Hispanic or Latino: 13 (100%) |
| **Age (mean, SD)** | (77, 6.272) |

- The Wake Forest University School of Medicine site plans to recruit more racial and ethnic minorities to create a study population that is more representative of the general population



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