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## Improving Response to Chemotherapy by Adding Physical Exercise in the Neoadjuvant Setting of Breast Cancer Patients –Study Protocol for the KEYMOVE trial

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**Purpose:** Improving the effectiveness of breast cancer (BC) treatment remains a major priority due to its high incidence and mortality. Neoadjuvant chemotherapy (NACT) is widely used in triple negative and HER2 positive disease, and in selected luminal HER2 negative cases. Evidence suggests that structured exercise may enhance treatment responses. This RCT aims to: (1) determine whether adding exercise training to NACT improves therapeutic efficacy; (2) explore biological mechanisms that may mediate exercise-related effects.

**Methods:** This 1:1 parallel group RCT includes 86 women with primary BC undergoing NACT. Participants are randomized, stratified by cancer subtype, to standard care or standard care plus a supervised exercise program. The intervention consists of three weekly sessions of combined moderate-to-vigorous aerobic and resistance training throughout NACT. The primary outcome is pathologic complete response (pCR), defined as the absence of invasive tumor in the breast and axillary nodes at surgery. Secondary outcomes include chemotherapy tolerance and compliance, systemic and tumor-specific immune responses, inflammatory biomarkers, maximal isometric strength (handgrip and quadriceps), exercise tolerance, physical activity, and quality of life. Assessments occur at baseline and post NACT. Relative dose intensity will be calculated at treatment completion, and patient reported outcomes will be collected weekly during chemotherapy. The sample size provides 80% power to detect differences in pCR, with analyses using a 95% confidence interval. The study is conducted at the Local Health Unit of Gaia/Espinho, Portugal, approved by the institutional ethics committee and registered under NCT05976815. Recruitment began on August 2023; by December 2025, 80 participants had been enrolled, with 60 having completed the trial.

**Conclusion:** This trial is among the first adequately powered RCTs to test whether structured exercise can enhance pCR in BC patients receiving NACT. Immune and treatment compliance analyses may clarify the mechanisms underlying exercise training impact on treatment efficacy.

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### Keywords

Treatment efficacy; Pathological response; Randomized controlled trial; Study protocol

### Conflict of Interest & Ethical Approval

yes

### Abstract submitters declaration

yes

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