

ACTIVATE: A pilot randomized activity coaching trial to increase vitality and energy during post-operative pelvic radiation therapy for endometrial cancer.

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Background: The ASCO-Society for Integrative Oncology guidelines strongly recommend exercise as a therapeutic strategy for cancer-related fatigue (CRF), advising that exercise regimens be tailored to each patient's capabilities. Despite this broad endorsement, at least two-thirds of cancer patients are unable to adhere to the recommendation of exercise due to symptoms and barriers, with women being more likely than men to report barriers to adherence to exercise. There is a lack of data on how to effectively integrate exercise into the treatment regimens of pelvic radiation therapy (RT). Most studies focus on other cancer types or male patients, leaving a significant gap in the literature regarding female patients with gynecological malignancies. Given the high prevalence of CRF and its impact on QoL, interventions reducing fatigue are vital. The primary objective of the ACTIVATE pilot trial (NCT06746428) is to evaluate the feasibility and acceptability of conducting a randomized trial with an exercise coaching program as the intervention in this patient population. Secondary objectives include estimating preliminary efficacy of exercise coaching on fatigue and health-related quality of life, quantifying baseline fatigue levels in our patient population, assessing eligibility criteria suitability, and exploring behavioral mechanisms and variables influencing intervention strength.

Methods: The study methods include randomization of immediate versus delayed intervention with attention-control of 16 women treated with total or modified radical hysterectomy and surgical staging for Stage I-IVA endometrial cancer and are planned to complete pelvic RT as part of their adjuvant treatment. The intervention is an exercise coaching program which will consist of weekly check-ins for 10 weeks with a certified oncology exercise coach with a goal to address readiness for exercise, identify barriers, and develop an individualized plan for exercise for each week with a goal of increasing activity to 150 minutes of moderate activity per week. The immediate-start group begins with the start of RT; the delayed-start group starts at 6-8 weeks post-RT. Participants will be asked to wear an activity monitor to track steps and moderate activity minutes, complete assessments of patient-reported fatigue (FACIT-Fatigue), bowel/urinary toxicity (EPIC), sexual function and satisfaction (PROMIS), and quality of life (PROMIS-29+2 Profile v2.1), and participate in a six-minute walk test (6MWT) at predefined time points throughout the study. Feasibility will be evaluated on a prior goal of 50% provider acceptability, 50% patient acceptability, 50% appropriateness of screening criteria, and 70% adherence to the coaching session and physical activity monitor. Enrollment began in January 2025 and accrual is expected to be complete within 6 months. Clinical trial information: NCT06746428. Research Sponsor: None.