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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: Women with endometrial cancer experience substantial symptom burden during adjuvant pelvic radiation therapy (PRT), with cancer-related fatigue among the most debilitating. Fatigue is exacerbated by recent surgery, older age, obesity, and treatment-related side effects, making exercise challenging. This trial evaluates the feasibility and preliminary efficacy of personalized exercise coaching delivered during post-surgical PRT versus initiating exercise 5-7 weeks post PRT, enabling assessment during treatment and early recovery.

Methods: Sixteen women with Stage I–IVA endometrial cancer scheduled to receive adjuvant PRT after total/modified radical hysterectomy are randomized to immediate or delayed coaching using an attention-control design. The intervention is a 10-week personalized exercise-coaching program with weekly sessions helping participants achieve ≥ 150 minutes/week of moderate activity. The immediate group begins coaching at PRT initiation; the delayed group 5-7 weeks post-PRT. Participants wear an activity monitor and complete patient-reported outcomes at baseline, post-PRT, 5-7w post-PRT, and 6-mo follow-up: fatigue (FACIT-Fatigue), bowel/urinary toxicity (EPIC), sexual function (PROMIS), and quality of life (PROMIS-29+2). Functional capacity is assessed via six-minute walk test (6MWT). Feasibility benchmarks: $\geq 50\%$ provider acceptability; $\geq 50\%$ patient acceptability; $\geq 50\%$ appropriateness of screening criteria; $\geq 70\%$ adherence to coaching and device wear. Enrollment began January 2025 and is expected to conclude January 2026, with follow-up completed by July 2026.

Preliminary Results: Thirteen participants have enrolled to date (54% non-Hispanic White, 15% non-Hispanic Black, 15% Hispanic, 8% Middle Eastern/North African). Baseline mean weight was 79.4 kg, height 63.6 inches, 6MWT distance 1168 meters. Six women were randomized to immediate start and 7 to delayed. Assessment completion is 100% at baseline, post-PRT, 6mo follow-up; 86% at 5-7w post-PRT. Three participants withdrew for unrelated reasons (PRT side-effects, medical issue, social hardship). Five have completed the study, all meeting feasibility benchmarks.

Conclusions: Early findings indicate good feasibility and acceptability, supporting the feasibility of delivering exercise coaching during PRT.

Keywords

Endometrial cancer; Pelvic radiation therapy; Pilot randomized trial; Exercise coaching; Cancer-related fatigue

Conflict of Interest & Ethical Approval

yes

Abstract submitters declaration

yes

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