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Home-Combo: an online home-based exercise intervention for women with breast cancer undergoing neoadjuvant chemotherapy: study protocol for a 2-arm pragmatic randomized controlled trial.

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Background. Chemotherapy side effects often cause dose reductions or delays in women with breast cancer (BC), and relative dose intensities below 85% are linked to poorer prognosis and reduced treatment efficacy. Exercise may modulate treatment response by influencing the tumor microenvironment. Recent evidence suggests that exercise may contribute to tumor regression during neoadjuvant treatment. Therefore, studies investigating the effects of exercise interventions on chemotherapy completion rates are needed. Home-based exercise is a convenient strategy during treatment and has been proven to be effective and beneficial for women with BC. However, to date, no study has analyzed the effects of these interventions on tumor regression in women with BC.
Purpose. This study describes a 2-arm pragmatic randomized controlled trial protocol targeting women with BC undergoing neoadjuvant chemotherapy.
Methods. Implemented in a real-world setting, this study compares an online structured and supervised group exercise intervention with an active control group during neoadjuvant chemotherapy. Ninety-eight participants with stage I-III BC scheduled to receive neoadjuvant chemotherapy will be enrolled continuously over one year. Primary outcomes are chemotherapy completion rate and tumor regression. Secondary outcomes include body composition, functional performance, self-reported physical activity, and general and BC-specific quality of life. Assessments will be conducted at baseline, mid-treatment, post-intervention, and 3-month follow-up.
Discussion. Home-based exercise training programs are safe for women with BC during treatment. However, structured and supervised interventions remain scarce. This study, involving participants undergoing neoadjuvant chemotherapy, allows evaluation of the intervention in the context of prehabilitation and its impact on post-surgery during follow-up. More studies are needed to analyze the effects of exercise on chemotherapy completion rates and tumor regression in BC. The results may demonstrate a reduced treatment exposure time, faster return to daily activities, fewer side effects, and improved overall and disease-related quality of life.

Trial registration: NCT06429189 (June 6th, 2024)

Keywords

Breast cancer; Home-based exercise; Neoadjuvant chemotherapy; Relative dose intensity; Tumor regression

Conflict of Interest & Ethical Approval

yes

Abstract submitters declaration

yes

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