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Title

Phase II feasibility study of a physical activity and dietary change weight loss intervention in a subset analysis of breast cancer survivors (SWOG S1008).

Permalink

<https://escholarship.org/uc/item/3484g6bw>

Journal

Journal of Clinical Oncology, 33(15_suppl)

ISSN

0732-183X

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Publication Date

2015-05-20

DOI

10.1200/jco.2015.33.15_suppl.9572

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Peer reviewed

Greenlee H, Lew D, Hershman DL, Pierce JP, Hansen K, Newman VA, Korner J, Sayegh A, Fehrenbacher L, Lo SS, Kemp JR, Rinn K, Robertson JM, Unger JM, Gralow J, Albain KS, Krouse RS, Fabian CJ Phase II feasibility study of a physical activity and dietary change weight loss intervention in a subset analysis of breast cancer survivors (SWOG S1008). *Journal of Clinical Oncology* 2015 33:15_suppl, 9572-9572

Abstract 9572

Background:

Weight loss among overweight and obese breast and colorectal cancer survivors is hypothesized to be associated with improved disease-free survival. Phase III trials are needed to test effective and implementable weight loss interventions in breast and colorectal cancer survivors.

Methods: We conducted a feasibility study of a 12-month community-situated physical activity and telephone-based dietary change weight loss intervention in female breast and colorectal cancer survivors. We report the primary outcomes for the breast cancer (BC) cohort. Sedentary postmenopausal women with prior Stage I-III BC and BMI ≥ 25 kg/m² were eligible. Primary objectives were to assess feasibility and weight loss at 12 months. Target accrual was 25 BC participants (ppts). Ppts were assigned a telephone counselor and given a 12-month membership to a local Curves fitness center, which offers a 30-minute circuit-based exercise program. Ppts were counseled 14 times over 12 months and were instructed to exercise 150 minutes/week, walk 10,000 steps/day, and decrease caloric intake by 500 kcal/day. The intervention would be considered feasible if full accrual was met within 10 months, $\geq 68\%$ of ppts met minimum goals for exercise (attend ≥ 2 exercise sessions/week for ≥ 36 weeks) and diet (reduce caloric intake by ≥ 100 kcal/day and/or increase fruit/vegetable intake by ≥ 1 serving/day) (adherence), and $\geq 68\%$ of ppts provided anthropometric measures at 12 months (retention).

Results: Among 25 evaluable ppts, median age was 57.3 years with median BMI 37.5 kg/m² (range 27.7-54.6), 64% Stage I, and median 2.1 years from diagnosis. Accrual occurred in 10 months, 80% of ppts provided anthropometric measures at 12 months, 96% of ppts met the diet goal, and 28% of ppts met the exercise goal. Thus feasibility goals were met, with the exception of exercise adherence as defined a priori. At 12 months, average weight loss was 7.6% (95% CI -3.9%, 19.2%) with median weight loss of 7.1%.

Conclusions: It is feasible to recruit and retain BC survivors in a multicenter weight loss trial using dietary change plus physical activity to achieve clinically meaningful weight loss over 12 months.

Clinical trial information: NCT01453452.