

# A pilot weight loss intervention in overweight and obese breast cancer survivors

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## Aim

To evaluate the feasibility and efficacy of a comprehensive group-based weight loss intervention in overweight and obese breast cancer survivors.

## Introduction

- Women with breast cancer commonly gain weight after diagnosis or are reported to be overweight or obese and/or have low levels of physical activity
- These factors are detrimental to quality of life and can lead to an increased risk of developing co-morbidities and new cancers and potentially an increased risk of cancer recurrence or decreased survival
- The high prevalence of weight gain, overweight and obesity is an important clinical issue in breast cancer survivorship and management
- There is a need for the development of efficacious weight loss and lifestyle interventions for breast cancer survivors

## Methods

### Study Design

- single-arm pilot study
- 24-week weight loss intervention
- group-based
- professionally-lead

### Eligibility criteria

- women diagnosed with early-stage breast cancer (stage I-IIIa)
- 18 years and older
- within 5 years of diagnosis
- completed treatment for at least 3 months (except hormone therapy)
- overweight or obese with a BMI = 25-35 kg/m<sup>2</sup>

The weight loss intervention was modeled after the Diabetes Prevention Program (DPP), which originally demonstrated a 58% reduction in the development of type 2 diabetes in overweight at risk US adults<sup>1,2</sup>.

### Study Intervention (n=14)

#### Modified Diabetes Prevention Program

- Diet Sessions
  - calorie-reduced, low fat diet (20% calories from fat)
  - 16 sessions with a Registered Dietitian
  - participants met weekly for the first eight weeks of the program, then biweekly
  - 16 session modules from the online resources (see website below)
- Physical Activity Sessions
  - 150 minutes per week of physical activity
  - program modified to include two weekly exercise sessions
  - supervised by a Physiotherapist and fitness trainers

### Primary Endpoint

- Body Weight
  - pre- and post-intervention
  - every four weeks during the study
  - 3 months (non-intervention) follow up

### Secondary Endpoints

- Body Mass Index
- % body fat (DEXA)
- lean body mass (DEXA)
- waist circumference
- hip circumference
- dietary intake (3-day food records)
- VO<sub>2</sub> max as a measure of aerobic fitness (maximal treadmill test)

## Results

Fourteen women were enrolled and completed the study. The mean age was 54 years and baseline BMI was 30 kg/m<sup>2</sup> (Table 1). The DPP program was well tolerated with no dropouts. Attendance (number of total sessions attended) at the fitness centre was 73% and diet sessions was 70%. There was a significant decrease in mean body weight (-3.8 kg) ( $p=0.01$ ) (Table 2) with absolute differences ranging from +2.5 to -13.8 kg (data not shown). In addition to weight loss, there were significant improvements in body composition including a decrease in % body fat (-2.4%) ( $p=0.01$ ), waist circumference (-4.2 cm) ( $p=0.03$ ), hip circumference (-5.5 cm) ( $p<0.01$ ) and BMI (-1.4 kg/m<sup>2</sup>) ( $p=0.01$ ). There was also a significant decrease in lean body mass (LBM) of -0.6 kg ( $p=0.001$ ). Results for other secondary endpoints included a significant increase in participant's physical fitness measured by mean VO<sub>2</sub> max, expressed by either kg/ml/min (+4.0) ( $p<0.001$ ) or L/min (+0.2) ( $p<0.001$ ). Dietary fat intake showed a small decrease that did not reach statistical significance ( $p=0.09$ ) and there was no statistically significant difference in caloric intake.

In the non-intervention 3 months follow period from the end of study to 9 months there were additional statistically significant improvements in body weight (-0.8 kg) ( $p=0.03$ ), waist circumference (-2.9 cm) ( $p=0.02$ ), and BMI (-0.3 kg/m<sup>2</sup>) ( $p=0.03$ ). There was no statistically significant difference in hip circumference (+0.2 cm) ( $p=0.80$ ). From baseline to 9 months, total weight loss was -4.6 kg ( $p<0.01$ ) with significant improvements in waist circumference (-8.1 cm) ( $p<0.01$ ), hip circumference (-5.5 cm) ( $p<0.001$ ) and BMI (-1.7 kg/m<sup>2</sup>) ( $p=0.01$ ). Overall 10 of the 14 women (79%) lost weight; five (36%) lost between 0-4.9% of their baseline weight, two (14%) lost 5-9.9% and four (29%) lost  $\geq$ 10% (Table 3). At 3 months follow up, there was virtually no change in this with the exception of fewer women categorized as gaining weight.

## Discussion

This pilot study, which adapted the Diabetes Prevention Program (DPP) in obese women with breast cancer, demonstrated modest but clinically significant improvements in body weight and physical fitness with some improvements in body composition. Overall participants lost 6% of their baseline body weight, which was slightly less than the DPP program goal of 7%. However, individual participant's change in body weight varied considerably from +2.6% to -18.9% during the 6 month intervention.

Weight loss intervention studies in women with breast cancer appeared in the 1980s when the clinical issue was first reported. Despite this growing problem only a limited number of small scale trials have been conducted since. Of these, few published weight loss intervention trials have used a combined dietary and physical activity-based approach<sup>3,4,5</sup>. While interventions differed, in these trials overweight breast cancer survivors lost statistically significant weight (1.2 to 5.7 kg) and/or experienced improvements in body composition similar in magnitude to this trial. Even less is known about effective weight maintenance interventions in women with breast cancer as most trials that do exist are relatively short in duration and have not generally included follow up. This pilot study reported outcomes of a 3 month non-intervention and demonstrated that maintenance of weight loss was feasible. Measured body weights (versus self reports) showed that women did not regain weight but rather were able to make further albeit marginal progress in losing weight. Limitations of this pilot study included the uncontrolled trial design and small sample size.

## Conclusion

- The pilot testing of the modified Diabetes Prevention Program in overweight and obese breast cancer survivors resulted in statistically significant and clinically meaningful weight loss during the 24-week study
- Participants also increased their aerobic fitness and showed some improvements in body composition
- Furthermore, weight loss and improvements in body composition were maintained during the 3 month non-intervention follow up
- Larger, longer term, controlled trials are needed to determine sustainability of weight loss and the effect on long-term outcomes

#### Diabetes Prevention Program (DPP):

#### Lifestyle Materials for Sessions 1-16 - Lifestyle Coach Materials and Optional Participant Handouts

Available as free downloads from the following website

[www.bsc.gwu.edu/dpp/lifestyle/dpp\\_dcor.html](http://www.bsc.gwu.edu/dpp/lifestyle/dpp_dcor.html)



TABLE 1: Baseline characteristics (mean  $\pm$ SD)

Variable	Baseline
Age (years)	55 $\pm$ 8
BMI (kg/m <sup>2</sup> )	30 $\pm$ 4
Time since diagnosis (months)	31 $\pm$ 21
Time since treatment completion (months)	24 $\pm$ 21
Physical activity moderate-vigorous (min per wk)	117 $\pm$ 66

TABLE 2: Anthropometrics, dietary intake and physical fitness (mean  $\pm$ SD)

Variable	Baseline	End of study(6 months)	Follow up (9 months)
Body weight (kg)	78.8 $\pm$ 10.7	75.0 $\pm$ 12.3*	74.2 $\pm$ 12.19†
BMI (kg/m <sup>2</sup> )	30.1 $\pm$ 3.6	28.6 $\pm$ 4.5*	28.3 $\pm$ 4.4†
Body fat (%)	42.4 $\pm$ 4.4	40.0 $\pm$ 6.0*	N/A
Lean body mass (kg)	42.1 $\pm$ 4.6	41.7 $\pm$ 4.9*	N/A
Waist circumference (cm)	99.4 $\pm$ 7.8	95.3 $\pm$ 10.3*	91.3 $\pm$ 7.3†
Hip circumference (cm)	112.2 $\pm$ 7.1	106.7 $\pm$ 10.3*	106.2 $\pm$ 10.81
Energy intake (kcal)	1594 $\pm$ 194	1533 $\pm$ 304	N/A
Dietary fat intake(g)	56 $\pm$ 13	45 $\pm$ 13	N/A
Dietary fat intake (% total kcal)	32 $\pm$ 6	27 $\pm$ 5	N/A
VO <sub>2</sub> max (kg/ml/min)	24.2 $\pm$ 3.3	28.6 $\pm$ 3.0*	N/A
VO <sub>2</sub> max (L/min)	1.9 $\pm$ 0.3	2.1 $\pm$ 0.24*	N/A

\*  $p < 0.05$  from baseline to end of study (at 6 months)

†  $p < 0.05$  from end of study (at 6 months) to post-study follow up (at 9 months)

N/A = not available at the follow up period

TABLE 3: Percent weight change

Percent weight change (#)	End of study (6 months)	Follow up (9 months)
Gained	3 (21%)	2 (14%)
Lost 0.0-4.9 %	5 (36%)	5 (36%)
Lost 5.0-9.9 %	2 (14%)	3 (21%)
Lost $\geq$ 10.0 %	4 (29%)	4 (29%)

## Selected References

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