Research Report

Effectiveness of profile by Sanford behavioral weight loss program for weight loss following endometrial cancer treatment

Maria Bell [a], Valerie Reed [b], Janet Wernisch [b], Natalie M. Papini [c], Stephen D. Herrmann [b,d,*]

[a] Sanford Health, Sioux Falls, SD, United States
[b] Sanford Research, Sioux Falls, SD, United States
[c] Northern Arizona University, Flagstaff, AZ, United States
[d] Profile by Sanford, Sioux Falls, SD, United States

A B S T R A C T

Objective: To examine differences in weight change and Body Mass Index (BMI) at 12 months among women in remission from endometrial cancer who enrolled in a behavioral weight loss (BWL) program and a matched patient control group.
Methods: Women (n = 22) were enrolled into the BWL program and were compared against a control group (n = 28) that accounted for age, BMI, cancer type, cancer stage, and treatment dates. The BWL program included weekly health coaching meetings that targeted nutrition, activity, and behavior change topics.
Results: Women enrolled in the BWL program completed 28.3 ± 14.1 appointments over 12 months resulting in an average weight change of -14.2 ± 7.8 kg ($-13.3 \pm 7.4\%$) at 6 months and -16.4 ± 12.5 kg ($-15.3 \pm 11.4\%$) at 12 months (all p < 0.001). Women in the control group had a weight change of -1.7 ± 8.4 kg ($-2.3 \pm 7.6\%$) at 12 months which was significantly different than the BWL condition (p < 0.001). BMI was significantly reduced in the BWL group at 6 months (-4.8 ± 4.5, $p < 0.001$) and 12 months (-5.2 ± 5.9, $p < 0.001$) and significantly different than in the control group at 12 months (-0.9 ± 3.2, $p = 0.007$).
Conclusions: The BWL program yielded clinically significant weight loss for endometrial cancer survivors. Future work should include longer follow up periods and include additional behavioral and psychosocial outcomes.

1. Introduction

Endometrial cancer is the most common cancer of the female reproductive organs in the United States with growing incidence and mortality rates (American Cancer Society, 2021; Onstad et al., 2016). Obesity (BMI ≥ 30 kg/m^2) is recognized as an independent risk factor for the development of endometrial cancer (Schmandt et al., 2011). Previous findings indicate that a 5 kg/m^2 increase in BMI is associated with an increased risk (59%) of developing endometrial cancer (Renehan et al., 2008). Furthermore, individuals with obesity experience higher rates of mortality from endometrial cancer than those without obesity. In a longitudinal prospective study of adults in the U.S., Calle and colleagues (2003) observed an increased risk of death for women with obesity who had diagnosed endometrial cancer (Calle et al., 2003). The evidence for the association between BMI and waist-to-hip ratio with endometrial cancer for premenopausal cancer and total endometrial cancer were evaluated as strong in a review of 171 meta-analyses (Raglan et al.,

2019). Other findings suggest that risk of obesity-related endometrial cancer can be reduced through sustained weight loss (Trentham-Dietz et al., 2006; Luo et al., 20192019). However, recent efforts to implement weight loss interventions in endometrial cancer survivors have produced little or no impact beyond usual care, or do not report results of 12 months or more (Haggerty et al., 2017; Zamorano et al., 2021; Hoedjes et al., 2017).

The purpose of the current study is to examine differences in weight change and BMI at 12 months among women in remission from endometrial cancer with obesity who were enrolled in a behavioral weight loss (BWL) program (Profile by Sanford) and a matched patient control group. Women enrolled in the BWL program received one-on-one health coaching as well as a comprehensive and nutritionally complete meal plan. The matched control group was selected using a cancer registry and medical records. Women in the matched control group received standard care, which included a discussion with the treating physician about weight loss as a way to improve health and decrease risk of the

patient's cancer recurrence at the post treatment visit. We hypothesized that participants in the BWL program would lose more weight and experience a greater reduction in BMI compared to participants in the matched control group at 12 months.

2. Methods

2.1. Overview, ethical approval

This was a non-randomized experimental study testing the primary hypothesis that women enrolled in the Profile by Sanford BWL program would be more effective in experiencing clinically significant weight loss than those in a matched control group receiving standard of care for endometrial cancer survivors with obesity. The primary study outcomes were weight loss (kg) at 12 months and BMI change at 12 months. The Institutional Review Board at Sanford Health approved this study.

2.2. Study enrollment and inclusion criteria

Patients visiting the Sanford Gynecologic Oncology Clinic between March of 2019 and January of 2020 were screened for eligibility to participate in the study. To be eligible, women needed to be 18 years of age and older, have been diagnosed with endometrioid endometrial cancer, no known metastatic disease, completed all treatment for endometrial cancer (i.e., no concurrent cytotoxic chemotherapy, radiation therapy, or further planned treatment; no evidence of active endometrial cancer as determined by physician) at least 2 months prior to study enrollment, have a BMI of 30 or higher, capable of following dietary guidelines established by the Profile by Sanford program, and provided an informed consent stating the purpose of the study. Individuals were excluded from participating in the study if they were actively receiving treatment for endometrial cancer or any other type of cancer, taking insulin for diabetes, taking corticosteroids for a chronic medical condition, bowel or stomach disorders, known liver disease, current kidney disease, or had any psychological or familiar condition that a medical professional believed would interfere with follow up and study compliance. Upon signing the informed consent, participants were assigned a study identification number and were contacted within one week to schedule their first health coaching session in person or through phone/video.

2.3. Profile by Sanford behavioral weight loss program

Profile by Sanford is a personalized weight loss and weight-loss maintenance program that utilizes a one-on-one lifestyle behavior coaching program focused on healthy diet and physical activity. Program membership includes health coaching, a Wi-Fi Smart scale that syncs with an interactive web platform and coaching application, along with a nutrition plan. Profile by Sanford recommends a balanced, reduced-calorie meal plan using a combination of grocery foods and meal replacements to ensure a nutritionally complete diet with adequate intake of vitamins and minerals. Meal replacements are used as a very specific tool to help simplify the program, improve nutritional value, and meet calorie goals while allowing the individual and Profile health coach to work through the behavioral components necessary to make long-lasting lifestyle changes. In addition to Profile foods, individuals are expected to purchase additional items from the grocery store to round out their nutrition plan (e.g., lean protein, 4 or more cups of vegetables per day, etc.). Behavior change and lifestyle modification is promoted through education and one-on-one consultations with a certified Profile coach. Members have access to 30-minute, weekly coaching appointments for the duration of the program and the ability to meet with a single coach or meet with different coaches.

2.4. Intervention

Participants were recruited during their standard follow-up oncology visits. After reviewing and signing an informed consent form, participants were enrolled in the 12-month study. A Profile health coach contacted each participant and scheduled a 1-hour initial session to review their past experiences, motivation, goals, and a brief health and lifestyle assessment. Ongoing health coaching appointments were available weekly for 30 min.

Profile health coaches utilize meal plan protocols to meet dietary needs and personalize the meal plan to adjust for individual needs or preferences. The nutritional program initially focuses on structured meal plans that include meal replacements. Over time, this transitions to fewer meal replacements and more grocery foods as individuals acquire and reinforce new knowledge, skills, and behaviors to support dietary changes (initial weight loss phase: 1000 to 1800 calories; 40–45% carbohydrates, 25–35% fat, 1.2–1.5 g/kg body weight at 24 BMI). In addition to nutrition, Profile coaches work with individuals on how to safely increase their daily activity level (goal of achieving $\geq$ 150 min per week of moderate intensity activity) and create a healthier lifestyle with behavior and habit changes. Health coaching is offered by phone, video, or in-person at Profile by Sanford locations. Participants were provided with Profile meal replacements free of charge for months 0 to 6 and were optional for purchase months 7 to 12 and had access to Profile coaching appointments for 12 months. Participant's weight and BMI were recorded through the Wi-Fi smart scale and automatically synced with their online account.

2.5. Matched patient control group

A matched control group was identified from Sanford's cancer registry and participants were matched on age, BMI, cancer type, FIGO stage (Stage 1A to 1B), and dates of treatment (2018 to 2020). Given some challenges associated with matched control groups, we evaluated the matched control group using the Synthetic Quality Control Checklist (Thorlund et al., 2020). Individuals in the matched control group attended clinic visits per standard of care at the physician's discretion. Participants continued their standard of care clinic visits, tests and procedures as directed by their physician based on each participant's needs. Participant's weight and BMI recorded during clinic visits were documented. If an individual had symptoms of recurrent cancer such as bleeding, pelvic pain, abdominal pain or new onset of shortness of breath, as part of standard care practices, they were imaged to see if they had recurrent disease.

2.6. Hypothesis and power

A power analysis was performed based on the initial study hypothesis that endometrial cancer patients enrolled in Profile by Sanford's weight management program would see at least 5% weight loss at 6 months. The sample size calculation was conducted a priori based on an expected 5% weight loss at 6 months at a 0.05 significance level. Based on these parameters, a sample size of 25 endometrial cancer patients was determined to give 90% power.

2.7. Statistical analysis

Data were summarized by mean $\pm$ standard deviation for all continuous characteristics. Statistical comparison between the intervention and control groups were performed with a Welch's *t*-test. Statistical significance was concluded if the p-value was <0.05 and R was used for all analyses (R Core Team, 2019).

3. Results

3.1. Enrollment and demographics of participants

A total of 28 women consented to participate, 3 failed eligibility screening allowing 25 to be enrolled in the intervention between March of 2019 and January of 2020. Three participants withdrew from the study (one changed her mind and decided not to participate, one withdrew and did not provide a reason, and one was removed due to unrelated health issues). Twenty-eight women were identified as matched controls. Average enrollment in the intervention group was 19.0 ± 17.4 months from their last treatment and the intervention group did not differ from those in the matched control by age, baseline weight, or baseline BMI (see Table 1). The twelve-month weight change hart review for the matched control group started 12.7 ± 3.1 months from their last treatment.

3.2. Weight management outcomes in intervention group vs. control

Participants in the intervention group completed 28.3 ± 14.1 health coaching appointments and experienced significant weight loss ($-15.3 \pm 11.4\%$) over 12 months. Women enrolled in the BWL intervention group lost significantly more weight and experienced greater reduction in BMI than women in the matched control group (see Table 2).

Fig. 1 presents individual data for percent weight loss for the BWL intervention and matched control group. In the BWL group, 80.0 % lost greater than 5% of baseline weight compared to 28.6% in the control group.

Fig. 2 displays the individual weight change pattern over 12 months. The pattern illustrates the majority of individuals lost weight in 6 months and maintained or continued to lose weight through 12 months, while a few individuals failed to lose significant weight or regained.

4. Discussion

This study showed that participants enrolled in the Profile BWL program lost significantly more weight than those in the matched control group who received standard care. Additionally, women in the intervention group experienced clinically significant weight loss from baseline to 12 months. These findings differ from other weight interventions intended for endometrial cancer survivors, such as the text-message-based intervention reported in Zamorano and colleagues (2021) in which no differences in weight change at 6 months were observed between participants randomized into the text-message-based intervention (-1.2 lbs) and enhanced usual care ($+0.3$ lbs) groups (Zamorano et al., 2021). At 12 months, 48.5% of participants in the intervention text message arm and 46.9% of those in enhanced usual care gained weight (Zamorano et al., 2021) compared to only 10% of individuals in the current study intervention. Taking the present study findings and those reported in Zamorano et al. (2021), the difference in weight outcomes could indicate that survivors of endometrial cancer may respond better to in-person or virtual videoconferencing programs than technology-based interventions delivered through an app alone with fewer interpersonal exchanges.

McCarroll et al. (2015) observed small but significant weight (-2.3 kg) and BMI (-0.8 kg/m^2) change from baseline to 1 month in women with a history of early-stage endometrial cancer and breast cancer who were instructed to use a mobile app that encouraged tracking physical

Table 1
Baseline participant characteristics.

Participant Demographics	Intervention (n = 22)	Control (n = 28)	P-value
Age	59.4 ± 11.5	58.4 ± 11.5	0.758
Weight (kg)	110.3 ± 21.0	112.0 ± 27.4	0.799
BMI	40.5 ± 7.8	41.6 ± 8.6	0.622

Table 2
Twelve-month weight and BMI change between intervention and control groups.

	Intervention (n = 22)	Control (n = 28)	P-value
Weight at 12 months (kg)	90.8 ± 21.0	110.3 ± 31.8	0.014
Weight change (kg) at 12 months	-16.4 ± 12.5	-1.7 ± 8.4	<0.001
Weight change (%) at 12 months	-15.3 ± 11.4	-2.3 ± 7.6	<0.001
BMI at 12 months	34.0 ± 7.4	40.7 ± 10.4	0.013
BMI change at 12 months	-5.2 ± 5.9	-0.9 ± 3.2	0.007

activity and nutrition (McCarroll et al., 2015). This mobile app intervention yielded less weight loss than the weight loss observed in this current study (-2.3 kg vs. -16.4 kg) and observed 30% attrition in 4 weeks vs the present study which had 0% attrition through 6 months and 10.2% attrition/lost to follow-up over months 7–12 (McCarroll et al., 2015). Furthermore, the intervention duration and follow up period is considerably longer in the current study (6 months vs. 1 month for duration of intervention; 12 months vs. 1 month of follow up). Given that lifestyle interventions for endometrial cancer survivors have been shown to reduce fatigue, improve physical functioning, increase physical activity levels, and can result in significant weight loss, it is imperative to further evaluate different lifestyle interventions to understand the most effective approaches for this target population (Smits et al., 2015). Health coaching appears to provide additional benefits beyond technology-based programs delivered remotely with minimal interpersonal contact for survivors of stomach, colon, lung, and breast cancers (Yun et al., 2020). In a multi-site randomized controlled trial aimed at evaluating the efficacy of health coaching and a web-based program on cancer survivor physical activity, weight, and distress management, results suggest improved psychological functioning for individuals experiencing both health coaching and the web-based program together (Yun et al., 2020).

This study observed significant individual variability within both the BWL intervention and matched control groups. This indicates that a small percentage of patients successfully lose weight through usual physician care and weight management advice and success improves considerably with additional BWL support. Further work is needed to identify patients early that do not respond to either physician led usual care for weight management or those in other behavioral programming. Early identification may allow for including additional support options (e.g., pharmacotherapy, behavioral health support, etc.) to improve short and long-term outcomes (Acosta et al., 2017).

Strengths of the current study include that a single gynecologic oncologist treated all the patients and gave the same advice on weight loss to each patient. Both the oncology clinic and health coaching program operate under the same integrated healthcare system. Participants were recruited while receiving care from the oncology clinic and given the option to participate in the study. The sample recruited in the current study is typical of endometrial cancer survivors, and as such, the findings reported in the current study are generalizable to the target population. The inclusion of a control group allows for comparisons between participants who were enrolled in the BWL intervention against those who received standard of care. The decision was made to use a matched control group instead of a waitlist control group due to ethical (withholding known treatment) and methodological (recruitment, retention) issues pertaining to a waitlist control (Kinser and Robins, 2013). Further, participants in a true control group have been shown to change behaviors. Findings indicate individuals assigned to a control group in a randomized clinical trial can improve drinking, physical activity, and chronic disease management without receiving any intervention materials or instruction to change behavior (Jenkins et al., 2009; Waters et al., 2012; Becker et al., 2003). Using a control group from the registry matched on key demographic categories minimizes the likelihood of participant reactivity for those in the control group (i.e.,
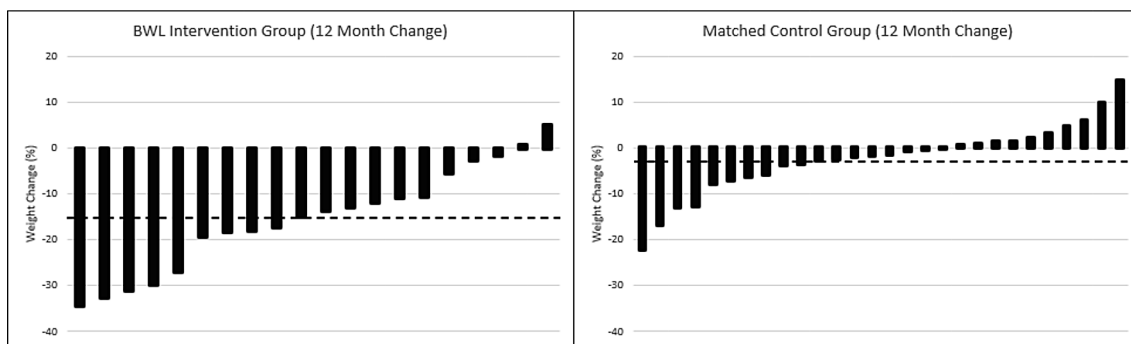
Fig. 1. Individual variability in weight change percent (%) from baseline to 12 months.
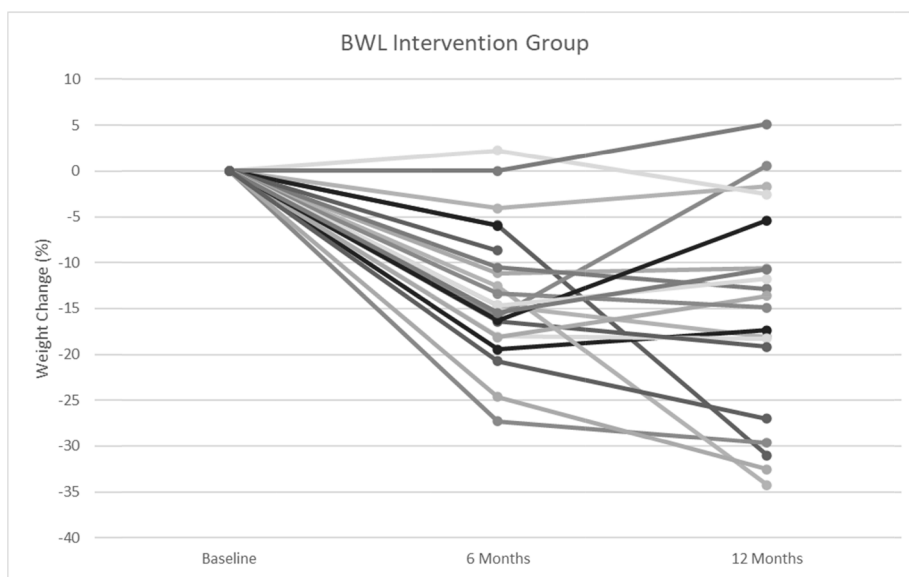

Fig. 2. Individual change over time in the behavioral weight loss (BWL) intervention group.

"Hawthorne effect") (PDQ® Adult Treatment Editorial Board, 2021).

The present study is not without limitations. First, participants who enrolled in the study received financial compensation in the form of a weight management program membership and program foods for 6 months. While this was determined by the Institutional Review Board to be fair compensation and not coercive, it did render access to these services more affordable (approximate value of $2,500) and accessible to individuals who otherwise may not have been able to afford or access the program. However, 68% of the women in this program continued with the program after 6 months at their own expense which may indicate the cost vs. perceived value was not prohibitive or participants had a socioeconomic status sufficient to support the cost. Given the reduction in weight observed in this study and the potential for associated reduced risk of endometrial cancer recurrence, future research should investigate the long-term healthcare cost savings of health coaching programs in endometrial cancer survivors. Further research in this area with this target population is needed to build evidence to support policy that would include health coaching programs as reimbursable for endometrial cancer survivors. Reimbursement is uniquely relevant to cancer survivors since many deplete financial resources throughout treatment and experience financial toxicity (Hall and Kahan, 2018).

Finally, the present study design incorporated a 12 month follow up period to determine if changes were maintained through one year. Weight regain is very common, with more than 80% of people experiencing weight regain after attempting weight loss (Anderson et al.,

2001; Nagle et al., 2013). Future work should consider adding longer-term follow up to determine the sustainability of weight loss in endometrial cancer survivors. This is especially important since weight cycling puts adult women at higher risk for endometrial cancer (Hart et al., 2020).

To conclude, future studies should continue to evaluate the efficacy of health coaching programs on the health and wellbeing of endometrial cancer survivors and extend follow-up periods to observe long-term cancer recurrence rates. From a holistic health perspective, additional outcomes such as behavioral (physical activity, dietary intake, etc.) and psychological (perceived stress, resilience, social support) should be included. By incorporating these additional outcomes, future work can improve the tendency of public health research to increase weight stigma by focusing solely on weight loss outcomes in research (Parkinson et al., 2020).

The present study findings have significant implications for practice by offering empirical support for a physician referred health coaching program as part of care after endometrial cancer treatment. Parkinson and colleagues (2020) reported patients are significantly more likely to enroll in health coaching and complete program requirements when they are referred by a physician. Furthermore, individuals significantly improved their health risks upon participating in a health coaching program (Parkinson et al., 2020). The current findings are aligned with those in Parkinson and colleagues (2020) and lend support to health coaching programs as an effective way to help endometrial cancer survivors after treatment.

Funding Disclosure

CRediT authorship contribution statement

Maria Bell: Conceptualization, Methodology, Investigation, Supervision, Writing – review & editing. **Valerie Reed:** Data curation, Formal analysis, Writing – review & editing, Visualization. **Janet Wernisch:** Methodology, Project administration, Validation, Writing – review & editing. **Natalie M. Papini:** Writing – original draft. **Stephen D. Herrmann:** Conceptualization, Methodology, Writing – original draft, Visualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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