

DETERMINANTS OF WEIGHT GAIN PREVENTION IN ADULT WOMEN

BY

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DISSERTATION

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## ABSTRACT

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Although the prevalence of overweight and obesity has remained stable in recent years, weight management remains a challenge for a large sector of the population. Particularly during young adulthood, women are at increased risk for excess weight gain. Rather than focusing on the treatment of excess body weight through energy restriction, which has proven to be ineffective in facilitating long-term weight loss, an alternative and more robust approach may be to emphasize the improvement of health and lifestyle behaviors to aid in prevention of weight gain over time. A 1-year randomized controlled trial of weight gain prevention was conducted in a sample of premenopausal women to determine the effects of a weight gain prevention intervention that included nutrition education on body weight (BW) change and other health outcomes over one year. This trial also aimed to compare the delivery of nutrition education by a registered dietitian to a counselor.

Women (n=87) were randomized to a control group (CON; n=29) or weight gain prevention intervention delivered by a registered dietitian (RDG; n=29) or counselor (CSG; n=29). Eighty-one women (mean±SD, age: 31.4±8.1 y; BW: 76.1±19.0 kg; body mass index: 27.9±6.8 kg/m<sup>2</sup>) completed baseline testing and were included in intention-to-treat analyses (CON=26; RDG=26; CSG=29). During the intervention period, women in the RDG and CSG groups attended 16 weekly and 8 monthly 1-hour nutrition education sessions. Anthropometric, blood pressure, dietary intake, physical activity, biochemical markers of health, eating behaviors, health perceptions and mediators of behavior change data were collected and evaluated at baseline and every three months thereafter. All data were analyzed using the Statistical Package for the Social Sciences (version 22.0, 2013).

The weight gain prevention intervention was successful in preventing weight gain over one year; however, BW change between the RDG, CSG and CON was not significantly different, and 62% of the original sample successfully prevented weight gain. Few differences were observed by group or over time using intention-to-treat analyses. Body fat percentage was significantly lower in the RDG compared to the CSG and CON at all time points (P<0.001). In the CON, systolic blood pressure significantly changed over time (P<0.001), and a group x time interaction for systolic blood pressure was observed (P<0.01). Intake of fruit servings per day

differed significantly at month 6 and 12 between the RDG and CON ( $P < 0.01$ ). No significant group differences were observed for additional anthropometric measurements ( $P > 0.01$ ), resting heart rate ( $P > 0.01$ ), systolic and diastolic blood pressure ( $P > 0.01$ ), macronutrient intake ( $P > 0.01$ ), food group servings ( $P > 0.01$ ), total energy expenditure ( $P > 0.01$ ) or biochemical markers of health ( $P > 0.01$ ). There were no significant effects of time for any anthropometric measurements ( $P > 0.01$ ), resting heart rate ( $P > 0.01$ ), diastolic blood pressure ( $P > 0.01$ ), dietary intake ( $P > 0.01$ ), total energy expenditure ( $P > 0.01$ ) or biochemical markers of health (all  $P > 0.01$ ). A cross-sectional examination of eating behaviors and grit, a non-cognitive personality trait, revealed that disinhibition was a significant predictor of BW and body mass index (BMI). Significant associations between grit and cognitive eating restraint (CER;  $r = 0.23$ ,  $P < 0.05$ ), disinhibition ( $r = -0.47$ ,  $P < 0.01$ ), hunger ( $r = -0.19$ ,  $P = 0.05$ ), BW ( $r = -0.24$ ,  $P < 0.05$ ) and BMI ( $r = -0.23$ ,  $P < 0.05$ ) were found. Over time, baseline grit did not predict BW change, but it was negatively associated with BW and BMI at month 12 ( $r = -0.25$ ,  $P < 0.05$ ;  $r = -0.23$ ,  $P < 0.05$ ). Disinhibition was the only predictor of month 12 BW, and women who successfully prevented weight gain had significantly lower levels of disinhibition at baseline ( $P < 0.05$ ) and significantly increased CER over the intervention ( $P < 0.05$ ).

Though the current weight gain prevention found no significant effects of nutrition education on weight gain prevention over time, a large proportion of individuals were able to maintain BW during the study interval. Further, disinhibition and changes in CER were related to successful weight gain prevention. Future interventions that address additional indicators of health and explore strategies to increase CER and manage disinhibition in order to facilitate prevention of weight gain over time are needed.

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## LIST OF ABBREVIATIONS

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ACC	American College of Cardiology
AHA	American Heart Association
ANCOVA	analysis of covariance
ANOVA	analysis of variance
BF%	body fat percentage
BMI	body mass index
BW	body weight
CER	cognitive eating restraint
CON	control group
CSG	counselor group
CV	coefficient of variation
DC	dark chocolate
EI	Eating Inventory
ELISA	enzyme-linked immunosorbent assay
ERD	energy-restricted diet
FITT	frequency, intensity, time and type
FM	fat mass
GOAL	Groningen Overweight and Lifestyle
Grit-S	Short Grit Scale
HDL-C	high-density lipoprotein cholesterol
HOMA-IR	homeostasis model of assessment-insulin resistance
IRB	Institutional Review Board
kcal	kilocalories
LDL-C	low-density lipoprotein cholesterol
MET	metabolic equivalent
NC	non-chocolate
NDSR	Nutrition Data System for Research
POP	Pound of Prevention
RDG	registered dietitian group
SCT	social cognitive theory
SD	standard deviation
SF-36	Short-Form 36 Health Survey
SNAP	Study of Novel Approaches to Weight Gain Prevention
svgs	servings
TG	triglycerides or triacylglycerides
TOS	The Obesity Society
UIUC	University of Illinois at Urbana-Champaign

## CHAPTER 1: Introduction

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While prevalence has stabilized in recent years, overweight and obesity remain major public health concerns for the United States population (1). Overweight and obesity are associated with metabolic abnormalities (2,3), decreased quality of life (4,5) and increased healthcare costs (6). While treatment efforts for overweight and obesity have focused primarily on weight loss through energy restriction, no methods have been effective in promoting long-term weight loss for a majority of individuals in the United States or decreasing the prevalence of overweight and obesity (7,8). Further, while weight loss is known to promote metabolic benefits (9-11), it may also result in some negative health effects such as an increased risk for weight cycling (12), disruption of hormonal milieu (13) and decreased bone mineral density (14).

It is obvious that a new approach to weight management is needed. Weight gain prevention is one such approach that removes the focus from energy restriction and weight loss and instead focuses on improving lifestyle behaviors to manage weight over time. Overweight and obesity generally do not develop rapidly; rather, they are the result of small, cumulative weight gains over time (15,16). Particularly, women are at highest risk for weight gain during young adulthood and midlife (15,16) as a result of various life transitions (17). Little is known regarding weight gain prevention, as few studies have addressed primary weight gain prevention (18-23) and none have included all individuals for which weight gain prevention is applicable, that is normal weight, overweight and obese individuals. Further, as determinants of weight gain prevention most likely differ between men and women, studies that examine one gender will help to inform gender-specific recommendations and intervention methods.

This dissertation examines the findings from a randomized controlled trial that sought to prevent weight gain over one year in normal weight, overweight and obese premenopausal women using nutrition education. Additionally, this research sought to compare the delivery of a weight gain prevention intervention by a registered dietitian (i.e., an individual with formal nutrition training) to a counselor (i.e., an individual with no formal nutrition training).



The primary aim of this research was to prevent the burden of obesity among adult women by identifying determinants of weight gain prevention as guided by the Social Cognitive Theory (24). Specific objectives for this research included:

- 1) Filling the scientific gap in the understanding of the determinants of weight gain prevention in women;
- 2) Aiding women in maintaining body weight, within 3%, over the study duration;
- 3) Providing general nutrition education and fitness knowledge to induce behavior change; and
- 4) Identifying optimal strategies and key recommendations for prospective weight gain prevention.

The first hypothesis was that women participating in a weight gain prevention intervention who were randomized to receive nutrition education would maintain body weight over a 1-year interval when compared to a control condition. Second, it was hypothesized that women receiving nutrition education from a registered dietitian would have less weight gain over the 1-year interval when compared to women receiving the same nutrition education from a counselor.

Within this dissertation, Chapter 2 reviews the literature and provides an overview of the current state of obesity, including current treatment approaches, and describes why a new frame of mind is necessary. The current body of research in relation to weight gain prevention is further examined and summarized in Chapter 2. Chapter 3 presents two preliminary studies that examined weight loss and weight loss maintenance in women. These studies took a quantitative and qualitative approach, and findings informed the design and intervention aspects of the current dissertation research. The methodology of the current randomized controlled trial for weight gain prevention is described in Chapter 4, and major outcomes and findings are presented in Chapter 5. Chapter 6 includes the results from a cross-sectional examination of the relationship between grit, a personality trait related to perseverance, and the eating behaviors of cognitive eating restraint, disinhibition and hunger. Grit was further

examined as a predictor of weight regulation over time in Chapter 7. Finally, Chapter 8 provides a brief summary of the major findings of this dissertation and offers opportunities and directions for future research. Supporting documentation, including Institutional Review Board approval and permission to reprint articles, are included in the Appendices.

Results from this comprehensive investigation further add to the meager body of evidence that has examined weight gain prevention and provide avenues for improving future interventions. In addition, this research provides support that weight gain prevention is relevant for all individuals, across healthy, overweight and obese body mass index categories, and aligns with the mission of public health to *prevent* diseases, such as overweight and obesity, and *promote* health rather than solely focus on *treatment* approaches for excess body weight.

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## CHAPTER 2: Literature review

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Excess body weight, in the form of overweight and/or obesity, is a growing global public health concern. While the prevalence of overweight and obesity has stabilized in recent years, more than two-thirds of adults in the United States, including sixty-some percent of women, remain overweight or obese (1), and it is estimated that the prevalence of overweight and obesity among women will reach 80% by 2022 (2).

Overweight and obesity generally result from gradual weight gain over decades, averaging one to two pounds per year (3-5). Rates of weight change have been estimated at 0.39 kilograms (0.86 pounds) per year for white American women and 0.54 kilograms (1.2 pounds) for black American women (6). Young adulthood has been identified as a stage of the lifespan during which individuals are at high risk of excess weight gain (6-9). For women, young adulthood encompasses many life transitions and potential stressors, such as pregnancy, postpartum, increased family responsibilities and changes in health status that may accompany aging (10). Consequently, weight management programs and interventions should target this period of the lifespan.

### ***The economic burden of obesity***

Obesity has great economic effects on the nation (2, 11-15). Obesity has been estimated to increase healthcare costs by \$3,508 per person each year, and in 2010, it was estimated that obesity among adults increased annual healthcare costs by nearly \$316 billion (13). By 2020, researchers estimate that \$394 to \$438 billion will be spent on direct healthcare costs related to obesity (2), and by 2030, this cost will escalate to roughly \$860 to \$957 billion or 16-18% of total healthcare costs (2). At the individual level, those with excess body weight have 30% higher healthcare costs, compared to individuals of normal body weight (12). Statistical models indicate that a 5-10% reduction in excess body weight (13) or a one percent decline in the predicted prevalence of obesity (14) may result in substantial healthcare cost savings, however, most individuals are unable to maintain weight losses (16-21) and return to previous baseline body weight within three to five years (17-19). Sustained levels of obesity prevalence (14),

which may be achieved by prevention of weight gain via behavioral lifestyle modifications, could result in similar cost savings by preventing or managing weight-related co-morbidities in the absence of weight change.

### ***Obesity and quality of life***

Indirect costs of overweight and obesity, including decreased quality of life (22,23), may have negative effects at the societal and individual levels (15). Decreased quality of life may be manifested in ways such as decreased self-esteem, lowered interest in activities and reduced mobility and physical functioning. Reductions in excess body weight have been shown to improve quality of life in the short term (24,25), specifically related to the Short-Form 36 Health Survey (SF-36) constructs of physical functioning, vitality, role-physical, mental health and general health (24); however, these improvements may be diminished over the long term, regardless of whether an individual is able to maintain weight loss (26). More research is needed to demonstrate the efficacy of weight loss through obesity treatment in improving quality of life (23) and how weight regain may impact quality of life. The effect of other non-weight related avenues to improve quality of life, including weight gain prevention, should also be explored.

### ***Treatment of excess body weight***

While weight loss via dieting or caloric restriction is the generally recommended treatment for excess body weight, it is only effective in reducing the prevalence of overweight and obesity if weight loss can be maintained (20). Undoubtedly, dieting and caloric restriction lead to short-term weight loss (20, 27-33); however, these losses are frequently not maintained over the long term (16-21). Regardless of the method or program used to induce weight loss, six months is the average length of adherence (17). Further, the likelihood of maintaining weight loss decreases over time (34). Within three to five years after initial weight loss, most individuals regain all of the weight lost, with half of this weight regain occurring in the first year following weight loss (17-19). Even more dismal, a review of 14 studies found that in eight of the studies reviewed, weight was regained to levels above participants' starting body weight

(20). Interventions that incorporate both dietary and physical activity components may be most effective in preventing weight regain (35,36) but long-term follow up (>24 months) is limited. Other factors found to delay or slow weight regain include face-to-face interventions (35) and extended care/continued contact (10,37). As it appears that weight loss maintenance is a missing piece of many weight loss trials and that most individuals are unable to maintain weight loss, it is difficult to classify diets, and even short-term weight loss, as effective treatments for excess body weight (20, 38). New approaches to understanding the determinants of weight gain prevention are necessary (38).

Although modest weight losses of 5-10% of body weight are associated with improvements in obesity-related risk factors, few studies support that these health benefits are maintained with weight regain (20, 39). Further, weight regain could lead to weight cycling, or repeated losses and gains of body weight. Although true relationships remain inconclusive, weight cycling has been associated with an increased risk for morbidity and mortality, possibly due to the negative effects on metabolic, psychological and mental outcomes (20, 40-42). Additionally, weight cycling has been found to be predictive of weight regain (21). Taken together, these findings demonstrate that long-term benefits of weight loss are minimal, and that weight cycling and/or weight regain may pose further health risks. Therefore, it may be time to reconsider weight loss as the most successful avenue for addressing the burden of excess body weight.

### ***Weight gain prevention: an alternative to weight loss***

Weight gain prevention may be a more robust alternative to weight loss. While small weight gains over the course of one year may seem clinically insignificant, these small weight gains accumulate over time and contribute to the development of overweight and obesity. Once excess body weight is present, weight loss and weight loss maintenance prove to be challenging for many individuals and success varies widely depending on an individual's behavior, physiology and environment. While behavior and environment can be altered, physiology and genetic predisposition are much less pliable. The treatment or intervention required to prevent weight gain is less intensive than that needed to promote weight loss (5)



and removes the burden or stigma placed on individuals to lose weight (38). Primary weight maintenance, also referred to as weight gain prevention, offers a more realistic avenue to curtail the obesity epidemic by slowing weight gain and mitigating risk factors associated with weight gain over time (43).

Additionally, weight gain prevention is applicable for all segments of the population, regardless of whether an individual is normal weight, overweight or obese. In individuals with overweight and obesity, weight gain prevention may play a role in decreasing the risk of developing concomitant diseases or other risk factors, or may aid in controlling or improving current diseases and related symptoms (44). Although obesity is associated with other co-morbidities and risk factors, it is important to note that not all individuals with obesity have, or will develop, metabolic abnormalities (45,46) and that weight gain prevention may play a role in the management and prevention of developing these abnormalities. Individuals with overweight are at greatest risk for becoming obese; therefore, weight gain prevention is especially important for this sector of the population (47). Promoting weight gain in individuals of normal weight also will help prevent the progression to overweight and/or obesity.

Weight loss may not be a realistic or appropriate goal for some individuals, and repeated weight loss attempts may have detrimental effects on health. One longitudinal study found that the probability of individuals with obesity to attain normal body weight status was just 0.8% for women (and only 0.5% for men) (48). For these individuals and others, prevention of additional weight gain may be a more appropriate treatment plan and target for treatment programs and interventions. Prevention of weight gain can be achieved through lifestyle and behavior changes which may result in improved health status, even in the absence of weight change.

### ***Weight gain prevention studies***

Primary prevention has been identified as the most affordable and effective method to prevent obesity and other chronic diseases (11), yet low quality evidence supports the effectiveness of interventions in reducing and/or maintaining body weight (44). One reason for the low quality of evidence is the fact that little work has targeted primary prevention of

obesity (Table 2.1). Instead, much of the current literature has focused on weight loss and weight loss maintenance, otherwise known as secondary weight maintenance (38). The first weight gain prevention trial was conducted nearly 30 years ago in normal weight adults (<115% of ideal body weight) between the ages of 25-74 years (49). This study compared the effects of low-intensity nutrition education and financial incentives on weight change to a no-contact control over a 12-month period. Newsletters that included general nutrition information regarding nutrition, physical activity and other lifestyle components were sent to participants who were randomized to the treatment group each month. With each newsletter, participants were asked to self-report body weight and any strategies used to prevent weight gain. A financial incentive was also included in the treatment intervention. For participants wanting or needing greater assistance in weight gain prevention, four intensive nutrition education sessions were offered around the 6-month mark of the intervention. At the end of 12 months, significantly more individuals in the treatment group (82%) maintained or lost weight as compared to the no-contact control group (56%), and the difference in weight loss between the two groups was significantly different (-2.1 pounds vs. -0.3 pounds).

Extending this early work, Jeffery and French investigated weight gain prevention over three years in adults between the ages of 20-45 years (50,51). Body weight was not used as entry criteria for the study; however, participants were overweight, on average. Participants were randomized to one of two low-intensity nutrition education groups or to a no-contact control group. Participants in both of the nutrition education groups received monthly newsletters that emphasized regular self-weighing, increased consumption of fruits and vegetables, decreased consumption of high-fat foods, and increased participation in exercise, specifically walking. Similar to the first weight gain prevention study, participants were asked to self-report body weight and answer questions related to the major themes emphasized by the newsletters. Semiannual nutrition and exercise classes were offered to education intervention participants as well. The education groups were identical in materials and messages, except that one group received a lottery incentive for returning the monthly postcard. After one year (50) and three years (51), there were no significant differences in weight change between groups; however, participants in the nutrition education groups reported a significant increase

in frequency of self-weighing (50,51). Of the entire study population, just 37% of participants maintained (or lost) weight over the 3-year period (51). Although weight-related behaviors were positively impacted by nutrition education and this was related to a decrease in weight gain over time, weight gain was not significantly different between individuals randomized to the treatment or control groups (51). An additional cross-sectional and prospective analysis of participants in the Pound of Prevention study that aimed to identify behaviors that predicted and/or accompanied weight change over time concluded that the determinants of weight regulation are multifactorial (52). Dietary fat intake and lack of physical activity were behaviors most consistently related to weight gain in men and women, while total energy intake was also positively associated with weight gain over time in women (52). Even though overall results of the Pound of Prevention study were not significant, the authors recommended several suggestions for future weight gain prevention programs, including more interactive interventions that include increased frequency of messaging, tailored information for participants and attention to motivational issues (51).

Levine and colleagues examined weight gain prevention over a 3-year period (2-year intervention plus 1-year follow-up) in normal weight and overweight women between the ages of 25-44 years (53). Participants were randomized to an information-only control group, a clinic-based nutrition education intervention or a correspondence-based nutrition education intervention. Women randomized to the clinic-based group attended 15 group meetings led by trained nutritionists and behavioral interventionists over the 2-year intervention; sessions were held biweekly for the first two months and bimonthly for the remaining 22 months of the study. The correspondence-based group received the same 15 lessons as the clinic-based group by mail along with a brief homework assignment that included a question about current self-reported weight. Upon randomization, women in the control group received a booklet (54) containing general wellness information. Over three years, there were no significant differences between groups in changes in body weight and body mass index (BMI), and nearly 40% of all participants, regardless of group assignment, lost or maintained body weight. More women in the clinic-based and control groups remained weight stable when compared to the correspondence-based group, but these differences were not significant. Overall, older age,

lower feelings of hunger and dieting status at baseline predicted weight gain prevention in this sample of normal weight and overweight women. Since neither intervention was found to be superior to the information booklet, the authors called for more innovative and intensive approaches, in addition to stronger public health messages, to aid in weight gain (and obesity) prevention.

The Groningen Overweight and Lifestyle (GOAL) study compared the effects of computer-guided lifestyle counseling by a nurse practitioner to usual care by a general practitioner on weight gain prevention and health status in overweight and obese men and women, between the ages of 40-70 years, with hypertension and/or dyslipidemia (55-57). Lifestyle counseling by the nurse practitioner included four individual visits and one telephone feedback session during the first year of the study (55,56) and one individual visit and two telephone feedback sessions during years two and three (57). A standardized computer software program that followed nutritional and behavioral guidelines was used by nurse practitioners to guide sessions with participants. Participants randomized to the control group received usual care defined as one, 10-minute visit with the general practitioner.

After one year, approximately 70% of all participants maintained or lost weight (55,56); this number decreased to 60% after three years (57). Significantly more individuals in the intervention group successfully maintained or lost weight after one year when compared to the control group (55,56), but these differences were not present three years later (57). After one year and three years, there were no significant differences in weight change between groups (55-57); however, men randomized to the intervention group significantly reduced body weight and waist circumference when compared to the control group after one year (55,56), but these differences were not maintained (57). Because significant effects were not seen in women, the authors hypothesized that more intensive interventions may be necessary to prevent weight gain in women (55,56). Lifestyle counseling by the nurse practitioner did result in a significant decrease in fasting blood glucose levels, but had no effect on blood pressure or lipid levels (57).

A medium-intensity behavioral intervention designed to prevention weight gain was evaluated in overweight and class 1 obese premenopausal black women between the ages of 25-44 years as part of the Shape Program (58). Usual care that included biannual general

wellness newsletters was compared to a weight gain prevention intervention that included weekly self-monitoring, monthly counseling calls with a registered dietitian, skills training tailored to behavior change goals and a 12-month gym membership. At one year, significantly more women in the intervention group maintained or lost weight as compared to women in the usual care group. Weight loss was significantly greater in the intervention group at the end of the intervention, and these significances were still present six months following the intervention. However, there were no significant differences between groups for changes in other measures including blood pressure, waist circumference, or glucose or lipid levels at 12 or 18 months.

Final results of the most recent weight gain prevention study, the Study of Novel Approaches to Weight Gain Prevention (SNAP), are not yet available (59). The SNAP program targeted weight gain prevention in normal weight and overweight young adults between the ages of 18-35 years. A minimal intervention control was compared to one of two novel self-regulation approaches to weight management over an average of three years. Individuals in both self-regulation intervention groups attended eight weekly group sessions and two monthly group sessions as part of the initial treatment, followed by monthly contact via telephone and/or email, but with one group focused on small, manageable behavior changes and the other group focused on periodic, large behavior changes. While final results are not yet available, it is hypothesized that both self-regulation approaches will be more successful in promoting weight gain prevention as compared to the control group, and that the large changes self-regulation approach will have the greatest influence on weight gain prevention.

In summary, few studies have targeted primary prevention of weight gain in adults, and the results of studies that have examined weight gain prevention are not encouraging. Just two of the six studies included in this review found significant impacts of interventions on weight gain over time (49,58). Interventions ranged from low-intensity nutrition education via newsletters to medium-intensity interventions that included group sessions with registered dietitians or trained nutritionists. Additionally, the amount of contact or education given to the control group varied between studies, ranging from absolutely no contact to general wellness information provided through a booklet or newsletter.

Even though body weight was not substantially impacted by interventions, researchers reported positive changes in dietary and lifestyle behaviors. Not all studies measured additional health outcomes, so it is unclear if these changes had positive effects on biomarkers or disease risk even in the absence of weight change. The studies examining weight gain prevention varied in participant characteristics. Four studies (49,50,55,59) included men and women, while two studies included only women (53,58). Age ranges were similar for most studies; however, participants in the GOAL study (55-57) were older, and the age range was wide in A Pound of Prevention (49) when compared to other studies. One limitation of the current body of weight gain prevention evidence is that previous studies have focused on either normal weight *or* overweight/obese populations (not both). More research is clearly needed to understand the determinants of weight gain prevention in order to effectively develop strategies for long-term weight management (38,60). Without such an understanding, individuals remain at risk for increased healthcare costs as well as other health complications related to excess body weight.

### ***Efficacy of registered dietitians in adult weight management***

The 2013 American Heart Association (AHA)/American College of Cardiology (ACC)/The Obesity Society (TOS) Guideline for the Management of Overweight and Obesity in Adults recommend a comprehensive lifestyle intervention that includes referrals to nutrition professionals, such as registered dietitians, to treat overweight and obesity (61). Registered dietitians are viewed as credible sources of nutrition information (10,62) and have been shown to positively impact health- and weight-related outcomes (63-70) while also decreasing healthcare costs (65,67). When compared to usual medical care, treatment that included registered dietitians decreased diabetes risk and improved glucose control over a 12-week period in adults with prediabetes (70). Over a 12-month period, treatment by registered dietitians decreased anthropometric measurements, increased quality of life and reduced usage of prescription medications in individuals with obesity and type 2 diabetes (64), resulting in a nearly \$4,000 decrease in healthcare costs per person (65). In men with hyperlipidemia, an average of three, 1-hour sessions with a registered dietitian over an 8-week period significantly reduced BMI, total cholesterol, low-density lipoprotein cholesterol and triglycerides which

resulted in a decrease in use of medications to manage hyperlipidemia and translated to an approximate saving of three dollars for every one dollar spent on medical nutrition therapy (67). While overweight and obese individuals who did not receive medical nutrition therapy were able to significantly reduce anthropometric measures and increase exercise frequency over a 2-year period, individuals who participated in medical nutrition therapy achieved greater decreases in body weight and BMI (69). An observational study of cardiac rehab patients found that nutrition education and counseling by a registered dietitian significantly decreased triglycerides, total cholesterol, low-density lipoprotein cholesterol, BMI and waist circumference when compared to general nutrition education delivered by cardiac rehabilitation staff members (63). Taken together, findings from previous research studies demonstrate that registered dietitians are an efficacious component of programs and interventions.

### ***The use of peer educators***

Although registered dietitians are food and nutrition experts who have completed education and experience requirements related to food, nutrition, health and behavior, the inclusion of registered dietitians in programs or interventions may prove to be a barrier. Limited time and lack of reimbursement have been cited as issues that prevent physicians from being more involved in the treatment of overweight and obesity (71); these reasons also may explain why the use of registered dietitians in programs and interventions is not widespread. However, the use of lay health educators or peers may be an alternative to registered dietitians, as inclusion of these individuals in programs and interventions has been associated with a decrease in chronic disease risk factors for diabetes and cardiovascular disease (72-76). In individuals with prediabetes, a 24-month lifestyle intervention delivered by community health workers resulted in significant reductions in body weight, BMI, waist circumference, insulin, insulin resistance and glucose as compared to enhanced usual care that included two visits with a registered dietitian (74). A unique aspect of this study was that the community health workers were recruited, trained and monitored throughout the intervention by registered dietitians who also provided support (74). West and colleagues compared lay health educators trained by

research staff with a wait-list control group in one, 12-session intervention for older adults modeled on the Diabetes Prevention Program (75). Compared to the control group, individuals in the intervention group experienced significantly greater weight loss and improved lifestyle behaviors (75). Similar findings were reported in a peer-led lifestyle intervention, although training of peers was not explained (76) and in a pilot study that evaluated the use of trained peer coaches to deliver weight loss treatment in African Americans with diabetes or prediabetes (72). Although peer coaches received in-depth training, findings from Dutton (72) should be interpreted with caution, as this pilot study did not include a control group. Another study that compared the facilitation of a 6-month weight loss trial by professional, peer and mentor coaches, found that individuals led by professional and peer coaches had the largest decrease in body weight but that all groups were able to significantly decrease body weight (73). Even without a substantial nutrition or health background, lay professionals are able to promote significant health improvements in a variety of populations with adequate training by trained health professionals. Registered dietitians can expand their field of reach and utilize their expertise by adequately recruiting, training, monitoring and supporting lay educators. As the availability of registered dietitians may be limited in certain areas, the use of lay educators can help to fill this gap while meeting the needs of communities and individuals and serve as a cost-effective alternative (73,74).

### ***Next steps in weight gain prevention***

With limited research addressing primary weight gain prevention, strategies for preventing weight gain over time remain largely unknown. As different strategies are required to achieve weight loss and weight loss maintenance, strategies for successful weight gain prevention most likely differ as well (10). Without more weight gain prevention programs and interventions, the determinants of weight maintenance cannot be identified and an impact on public health and obesity prevalence cannot be made. Therefore, more programs and interventions are necessary to examine the feasibility of weight gain prevention and the underlying determinants that lead to gradual weight gain over time. These interventions should include individuals of all weight status categories, and gender should be separated as



determinants and strategies most likely differ between men and women (10,77). The intensity of future interventions should also be considered, as should the mode of delivery and who delivers the information. More trials including registered dietitians and adequately trained peer educators are necessary.

Due to the limited research in this area, there is an incomplete understanding of weight gain prevention. In order to gain a more comprehensive view, it is necessary to build upon past findings to develop optimal approaches to adult weight management. With potential benefits such as reduced healthcare costs, decreased obesity prevalence and improvement of chronic disease risk factors, weight gain prevention is a topic worthy of future exploration.

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Table 2.1 Studies of weight gain prevention in adults.

Authors	Population	Intervention	Duration	Results
Forster JL, Jeffery RW, Schmid TL, Kramer FM. Preventing weight gain in adults: a pound of prevention. <i>Health Psychol.</i> 1988;7:515-25.  <i>A Pound of Prevention</i>	Men and women (n=219)  25-74 years  Normal weight (<115% of ideal body weight)	Treatment group: Received monthly newsletters relating to weight management and participated in a financial incentive system; offered an optional 4-session education course in the sixth month of the program.  No-contact control.	1 year	Mean weight change was significantly greater in the treatment group compared to the control group.  Treatment had a stronger effect in men, older individuals (51+ years) and nonsmokers.
Jeffery RW, French SA. Preventing weight gain in adults: design, methods and one year results from the Pound of Prevention study. <i>Int J Obes Relat Metab Disord.</i> 1997;21:457-64.  Jeffery RW, French SA. Preventing weight gain in adults: the pound of prevention study. <i>Am J Public Health.</i> 1999;89:747-51.  <i>Pound of Prevention</i>	Men and women (n=809)  20-45 years  No weight criteria	Education only: Received monthly newsletters and optional low-cost intervention activities every 6 months.  Education + incentive: Received the same newsletters plus a lottery incentive for participation.  No-contact control.	3 years	Weight gain did not differ significantly by treatment group.  Individuals in intervention groups reported favorable changes over time in frequency of weighing and healthy dieting practices compared to those in the control group.

Table 2.1 (cont.)

Levine MD, Klem ML, Kalarchian MA, et al. Weight gain prevention among women. Obesity (Silver Spring). 2007;15:1267-77.	Women (n=284) 25-44 years Body mass index <30 kg/m <sup>2</sup>	Clinic-based group: Attended 15 group meetings over a 24-month period.  Correspondence course group: Received 15 lessons by mail, identical in content to the clinic-based group, over a 24-month period.  Information-only control: Received a booklet containing information about the benefits of weight maintenance, low-fat eating and regular physical activity.	2 year intervention  1 year follow-up	Intervention had no significant effect on weight over time.  Predictors of weight gain prevention: older age, low hunger at baseline, not on a diet at baseline, increased dietary restraint and decreased dietary disinhibition over time.
ter Bogt NC, Bemelmans WJ, Beltman FW, Broer J, Smit AJ, van der Meer K. Preventing weight gain: one-year results of a randomized lifestyle intervention. Am J Prev Med. 2009;37:270-7.	Men and women (n=457) 40-70 years Body mass index 25-40 kg/m <sup>2</sup>	General practitioner (GP) group: Usual care.  Nurse practitioner (NP) group: Lifestyle counseling consisting of 4 individual visits and 1 telephone feedback session (year 1) and 1 individual visit and 2 feedback sessions (years 2 and 3).	3 years	Mean weight loss was significantly greater in NP men compared to GP men at one year; there were no significant differences between women in the NP and GP groups.  After three years, there were no significant differences in weight change between groups.
ter Bogt NC, Milder IE, Bemelmans WJ, et al. Changes in lifestyle habits after counselling by nurse practitioners: 1-year results of the Groningen Overweight and Lifestyle study. Public Health Nutr. 2011;14:995-1000.	Hypertension and/or dyslipidemia			

Table 2.1 (cont.)

ter Bogt NC, Bemelmans WJ, Beltman FW, Broer J, Smit AJ, van der Meer K. Preventing weight gain by lifestyle intervention in a general practice setting: three-year results of a randomized controlled trial. Arch Intern Med. 2011; 171:306-13.

*Groningen Overweight and Lifestyle (GOAL) Study*

<p>Bennett GG, Foley P, Levine E, et al. Behavioral treatment for weight gain prevention among black women in primary care practice: a randomized clinical trial. JAMA Intern Med. 2013;173:1770-7.</p>	<p>African American women (n=194)  25-44 years  Body mass index 25-34.9 kg/m<sup>2</sup></p>	<p>Intervention group: Received tailored behavior change goals, weekly self-monitoring via interactive voice response, monthly counseling calls, tailored skills training materials and a gym membership.  Usual care control group: Received newsletters that covered general wellness topics every 6 months.</p>	<p>1 year intervention  6 month follow-up</p>	<p>Mean weight and body mass index changes were significantly larger in the intervention group compared to the control group at one year and these changes were sustained at 18 months.  No differences between groups in changes in waist circumference, blood pressure, glucose or lipid levels.</p>
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*Shape Program*

<p>Wing RR, Tate D, Espeland M, et al. Weight gain prevention in young adults: design of the study of novel approaches to weight gain prevention (SNAP) randomized controlled trial. BMC Public</p>	<p>Men and women (n=600)  18-35 years  Body mass index 21-30 kg/m<sup>2</sup></p>	<p>Self-regulation + small behavior changes: Attended 8 weekly group sessions and 2 monthly sessions (year 1) and 2 annual 4-week refresher courses (years 2 and 3). Taught to make small daily changes (~100 kcal) and to</p>	<p>1 year intervention  3 year average follow-up</p>	<p>Not yet published.</p>
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Table 2.1 (cont.)

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Health. 2013;13;300. doi:  
10.1186/1471-2458-13-300.

*Study of Novel Approaches to  
Weight Gain Prevention  
(SNAP)*

accumulate 2000 additional  
steps per day.

Self-regulation + large behavior  
changes: Attended 8 weekly  
group sessions and 2 monthly  
sessions (year 1) and 2 annual 4-  
week refresher courses (years 2  
and 3). Taught to create a  
weight loss buffer of 5-10  
pounds once per year to protect  
against weight gain.

Self-guided behavior change  
(control): Received 1 face-to-  
face group session and an  
overview of Large and Small  
Changes approaches.  
Participants self-selected their  
desired approach.

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## CHAPTER 3: Preliminary research

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In this chapter, findings from preliminary research are presented. Completed studies focus on weight loss and weight loss maintenance in women, and these findings have provided the foundation for the current dissertation research. The first study discusses results from an original 18-week weight loss intervention (1), while the second presents findings from a follow-up qualitative study of participants that completed the original weight loss trial in its entirety (2).

The first study describes a weight loss intervention that was designed to address issues related to energy restriction, discretionary calories and the inclusion of portion-controlled sweet and savory snacks within an energy-restricted diet. It was hypothesized that the inclusion of, rather than total elimination of, portion-controlled sweet and savory snacks would result in better adherence to the energy-restricted diet while promoting beneficial changes in body weight, blood pressure and other metabolic outcomes. While findings from this initial weight-loss intervention demonstrated that weight loss and other favorable metabolic changes are possible while consuming an energy-restricted diet that includes portion-controlled snacks (1), this study did not provide clarity about emotional and/or cognitive factors that may influence weight loss success or why some individuals were more successful in achieving weight loss goals when compared to others.

A qualitative follow-up study was conducted to gain a more comprehensive and deeper understanding of facilitators and barriers related to weight loss and weight loss maintenance in women participating in the initial intervention. Focus groups revealed that planning ahead, portion control, basic nutrition education, self-motivation, accountability to others, social support and mindfulness and awareness of food choices are major facilitators to weight loss and weight loss maintenance success. Major barriers included lack of accountability and social support, life transitions, environmental pressures, internal factors and health status changes (2) Attention to these barriers and facilitators has been given in developing the current weight gain prevention trial described in Chapter 4.

Collectively, these two studies demonstrate that flexible dietary approaches can promote beneficial changes in body weight; however, maintenance of weight loss remains a challenge for many women. As a majority of female participants were unable to maintain weight loss over time, these studies support the need for weight management strategies to prevent inappropriate weight gain over time. In combination with findings from other research studies, weight gain prevention may be a more sustainable and appropriate target than weight loss alone. Following the presentation of this preliminary work, Chapter 4 further describes the methodology for the current dissertation research.

## References

1. This article previously appeared in its entirety as Sharon M. Nickols-Richardson, Kathryn E. Piehowski, Catherine J. Metzgar, Debra L. Miller and Amy G. Preston. Changes in body weight, blood pressure and selected metabolic biomarkers with an energy-restricted diet including twice daily sweet snacks and once daily sugar-free beverage. *Nutr Res Pract.* 2014;8(6):695-704; doi:10.4162/nrp.2014.8.6.695.[Epub ahead of print]. This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0/>) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.
2. This article previously appeared in its entirety as Metzgar CJ, Preston AG, Miller DL, Nickols-Richardson SM. Facilitators and barriers to weight loss and weight loss maintenance: a qualitative exploration. *J Hum Nutr Diet.* 2014 Sept 18. doi: 10.1111/jhn.12273. [Epub ahead of print]. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is noncommercial and no modifications or adaptations are made.

## **Changes in body weight, blood pressure and selected metabolic biomarkers with an energy-restricted diet including twice daily sweet snacks and once daily sugar-free beverage<sup>1</sup>**

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**BACKGROUND/OBJECTIVES:** The type of sweet snack incorporated into an energy-restricted diet (ERD) may produce differential effects on metabolic improvements associated with body weight (BW) loss. This study compared effects of incorporating either twice daily energy-controlled dark chocolate snacks plus once daily sugar-free cocoa beverage (DC) to non-chocolate snacks plus sugar-free non-cocoa beverage (NC) into an ERD on BW loss and metabolic outcomes.

**MATERIALS/METHODS:** In an 18-week randomized comparative trial, 60 overweight/obese premenopausal women were assigned to DC (n = 30) or NC group (n = 30). Dietary intake was measured at baseline and week 18, and BW, anthropometrics, blood pressure (BP) and serum glucose, insulin and lipid concentrations were measured at baseline, and weeks 6, 12 and 18. Data were analyzed using repeated measures ANOVA.

**RESULTS:** Using intention-to-treat analysis, women in DC and NC groups reduced energy intake (both  $P < 0.001$ ) and lost  $4.4 \pm 0.6$  kg and  $5.0 \pm 0.9$  kg (both  $P < 0.001$ ), respectively. Both groups lowered systolic and diastolic BP [DC = 2.7 ( $P < 0.05$ ), 2.7 ( $P < 0.01$ ); NC = 3.4 ( $P < 0.01$ ), 4.2 ( $P < 0.01$ ) mmHg, respectively]. Glucose and insulin concentrations decreased by 0.72 mmol/L ( $P < 0.001$ ) and 13.20 pmol/L ( $P < 0.01$ ) in DC group and by 0.83 mmol/L ( $P < 0.001$ ) and 13.20 pmol/L ( $P < 0.01$ ), respectively, in NC group. Total cholesterol increased in NC group ( $P < 0.05$ ), with no significant lipid changes in DC group. There were no significant differences in biomarker outcomes between groups.

**CONCLUSIONS:** Overweight/obese premenopausal women following an 18-week ERD that included either DC or NC sweet snack and sugar-free beverage lost equivalent amounts of BW and improved BP measurements and glucose and insulin concentrations.

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<sup>1</sup>This article previously appeared in its entirety as Sharon M. Nickols-Richardson, Kathryn E. Piehowski, Catherine J. Metzgar, Debra L. Miller and Amy G. Preston. Changes in body weight, blood pressure and selected metabolic biomarkers with an energy-restricted diet including twice daily sweet snacks and once daily sugar-free beverage. *Nutr Res Pract.* 2014;8(6):695-704; doi:10.4162/nrp.2014.8.6.695.[Epub ahead of print]. This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0/>) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.



## INTRODUCTION

Overweight and obesity have become major public health concerns as 67 to 75% of adults in the United States (U.S.) are now affected [1]. Individuals with excess body weight (BW) spend 30% more on healthcare than those of normal BW, due to the increased incidence of co-morbidities such as hypertension, diabetes and heart disease [2]. To improve current health status and prevent future complications, the primary treatment for these individuals is reduction of excess adiposity through moderate BW loss [3]. The key dietary objective for inducing BW loss is a reduction in total daily energy intake below energy needs [4].

Many weight-loss diets and diet programs restrict all high-fat and/or high-sugar snack foods [5,6,7,8]. Allowing individuals to consume snacks that are normally enjoyed in energy- and portion-controlled amounts as part of an energy-restricted diet (ERD) may make adherence easier and potentially increase diet satisfaction, because habitual eating patterns are emphasized, and there is less dramatic alteration in food choices [9]. Chocolate is one of the most commonly liked and widely consumed sweet snacks among women in the U.S. and around the world [10,11], with approximately one-half of women reporting weekly consumption [12]. In addition, U.S. women are more likely than men to consume sweet foods such as ice cream, pastries and non-chocolate candy on a regular basis [11].

Chocolate as a sweet snack food is of particular interest, due to its volume of consumption [13], likeability [10] and pleasing sensory properties [12]. Epidemiologic studies suggest that chocolate intake is inversely related to body mass index (BMI) [14] and reduced risk of low high-density lipoprotein-cholesterol (HDL-C) and other metabolic syndrome indicators [13,15]. Further, previous studies suggest that consumption of chocolate and cocoa, specifically dark chocolate, may have beneficial effects on blood pressure (BP) [16,17,18,19,20,21], fasting blood glucose [20,22], insulin sensitivity [16,23,24] and blood lipids [17,19,25,26]. Cocoa is rich in minerals and phytonutrients, namely flavanols, including catechin, epicatechin and proanthocyanidins (PACs), and due to the higher cocoa content, dark chocolate may confer the greatest metabolic benefits when compared to milk or white chocolate [27,28].

Dark chocolate is commonly regarded as an energy-dense food [29] and excess consumption of any energy-dense food may have adverse metabolic effects, including weight gain. Therefore, women attempting BW loss often withhold chocolate and other sweet snacks from their diet. While several short-term (i.e., 2 to 8 weeks) studies have examined changes in BW following consumption of dark chocolate [30], only one study has compared the effects of dark chocolate against non-chocolate intake specifically on changes in BW and body composition during energy restriction in overweight/obese women [9]. In this feasibility study, inclusion of a dark chocolate or non-chocolate sweet snack as part of an ERD resulted in losses in BW, fat mass (FM) and body fat percentage (BF%), with no significant differences between the two snack groups. The sample size of this pilot study was small, and outcomes were limited to body composition without further exploration of biomarkers of metabolic health [9].

The aim of the current 18-week randomized intervention was to compare effects of incorporating twice daily dark chocolate snacks plus once daily sugar-free cocoa beverage (DC group) to twice daily non-chocolate snacks plus once daily sugar-free non-cocoa beverage (NC group) into an ERD with a typical macronutrient distribution [31] on BW loss and metabolic outcomes in free-living premenopausal women with overweight/obesity. Outcome measures included estimated energy intake, BW, anthropometric and BP measurements as well as serum glucose, insulin and lipid concentrations. Based on emerging evidence that dark chocolate and cocoa may modulate obesity, it was hypothesized that inclusion of dark chocolate and cocoa into an ERD would result in a significantly greater decrease in BW and more favorable improvements in metabolic indicators of health, compared to inclusion of non-chocolate and non-cocoa products.

## **SUBJECTS AND METHODS**

### *Participants*

Participants were recruited from central Pennsylvania, U.S., by word-of-mouth, newsletter and newspaper advertisements, electronic-mail notices and flyers posted in the local community. Two-hundred three women provided verbal consent for an initial telephone screening and were assessed for study eligibility; 85 were enrolled in the study. Due to a

relatively lengthy recruitment interval, 25 women withdrew before baseline testing was completed for a final sample size of 60 women (Figure 3.1).

The current dietary intervention included women ages 25 to 45 years with a BMI of  $\geq 25.0$  and  $< 43.0$  kg/m<sup>2</sup>. Women were moderately physically active ( $\leq 5$  hours of planned exercise/week), eumenorrheic ( $\geq 8$  menstrual cycles/year) and of self-reported stable BW ( $< 5\%$  change in BW for at least six months before study participation). Further inclusion criteria included a score of  $< 50$  on the Zung Self-Rating Depression Scale/Status Inventory and no intolerance, aversion or allergy to chocolate. Exclusion criteria included women who currently smoked, were pregnant or attempting to become pregnant, had a hysterectomy and/or ovariectomy without hormone replacement therapy and those who used oral contraceptives for  $< 2$  years in duration (if used). Women who used medications, including steroid or thyroid hormones, bisphosphonates, anticonvulsants and glucocorticoids, or consumed  $\geq 40$  grams of chocolate per day (i.e., equivalent of one standard chocolate bar or more/day) were also excluded. All study participants underwent medical examinations by their personal healthcare providers to obtain measured and reliable values for height, BW and BMI to ascertain inclusion criteria was met.

Written informed consent was provided by all participants before entry into the study. The Institutional Review Board (IRB) for Research Involving Human Subjects at The Pennsylvania State University (PSU; University Park, PA, U.S.) conducted a full review of the study procedures and approved the study protocol (PSU-IRB#29543).

### *Study design*

This was an 18-week randomized, parallel-arm, comparative dietary intervention in which participants were enrolled in two cohorts (July-December 2009 and March-July 2010). After enrollment of each cohort, women were stratified by baseline age, BMI and physical activity and then randomly assigned to either the DC group (n = 30) or the NC group (n = 30).

### *Dietary intervention*

Participants in both groups followed an ERD with a macronutrient composition of 50% carbohydrate, 30% fat and 20% protein designed to induce approximately 0.91 kg of BW loss per week by consuming 2,092 fewer kJ per day than required for energy balance. Baseline energy levels were set between 5,439 and 7,531 kJ per day as determined using the Harris-Benedict equation [32].

Women in both groups were administered portion-controlled and energy-matched snacks and beverages. Women in the DC group consumed one, 236 mL sugar-free natural cocoa beverage (The Hershey Company, Hershey, PA, U.S.) each day (272 kJ/day) and one 1.45 oz dark chocolate tasting square (Hershey's® Extra Dark® dark chocolate, The Hershey Company) at two intervals each day (377 kJ/day). Women in the NC group drank one, 236 mL sugar-free cocoa-free vanilla beverage (The Hershey Company; 272 kJ/day) each day and consumed two non-chocolate sweet snacks (fruit-flavored licorice stick; The Hershey Company) each day (377 kJ/day) at the same daily intervals as the DC group. Participants in both groups were instructed to not consume additional cocoa or chocolate products throughout the 18-week intervention beyond the snack and beverage assignments. Women in the DC group consumed 270 mg of flavanols (PACs 1-10) per day from dark chocolate snacks and the sugar-free cocoa beverage [16,17], and women in the NC group consumed 0 mg of flavanols per day from non-chocolate snacks and the sugar-free non-cocoa beverage.

A registered dietitian educated participants on how to follow the ERD, which was based on a food exchange system. Women were assigned a certain number of servings from each of six exchange groups to promote a flexible dietary approach that approximated usual intake except for energy restriction and inclusion of assigned beverages and twice daily snacks. Three main principles were emphasized, including portion control [33,34], planning ahead for meals [35] and consuming vegetables to satisfy an acute hunger sensation [36]. Handouts that contained food options, dietary patterns and individualized meal plans specific to energy levels were provided.

All women attended weekly nutrition education classes that covered topics such as general nutrition information, dining in restaurants, food selection, food preparation and recipe modification. Problem-solving and motivational concerns also were discussed and addressed.

Education sessions were specific to DC or NC group; however, topics were the same for both groups, and one registered dietitian led all of the education sessions to maintain consistency between groups. Snacks and beverage mixes were dispensed at education sessions, and compliance with snack and beverage intervention was assessed by participant self-report and concurrent investigator-conducted snack counts; compliance was defined as intake of  $\geq 85\%$  of weekly snacks and beverages based on group assignment. Upon completion of the study, participants received monetary compensation of \$80 (U.S.).

### *Outcome measures*

Dietary intake was evaluated at baseline and week 18. Anthropometric, physical activity and BP measurements were completed and whole blood samples were collected at baseline, week 6, week 12 and week 18.

### *Dietary intake assessment*

Dietary intake was estimated using 4-day food records. Women recorded all foods and beverages consumed on three non-consecutive weekdays and one weekend day in the week before measurement sessions at baseline and week 18. Handouts containing pictures of standard serving sizes of different foods and beverages were provided to aid in recording intake. Food records were evaluated using Food Processor<sup>®</sup> dietary analysis software (version 10.6.0, 2010, *esha* Research, Salem, OR, U.S.) for estimated average daily intake of total energy (kJ); carbohydrate, fat, protein and alcohol (% of total kJ); total sugar (g), fiber (g), saturated fat (g) and cholesterol (g); and sodium (mg).

### *Anthropometric measurements*

Standing height (cm) was measured using a stadiometer (Seca 700, Hamburg, Germany), and BW (kg) and BF% were measured using an electronic scale (410GS, Tanita Corporation, Arlington Heights, IL, U.S.); height and BW measurements were used to calculate BMI for each participant. Using a spring-calibrated measuring tape (Gulik II, Country Technology, Gay Mills, WI, U.S.), two measurements each of the waist at the narrowest point above the belly button

and hips at the widest part of the buttocks were taken to the nearest 0.1 cm and averaged. For all measurements, women were dressed in lightweight clothing without shoes.

#### *Physical activity*

Physical activity was estimated using the Stanford 7-day Physical Activity Recall Scale [37]. For seven consecutive days before a measurement session, participants recorded number of hours slept, spent in front of a television or computer screen and engaged in moderate, hard and very hard activity. Total hours of moderate, hard and very hard activity were summed from the recall scale and divided by seven to estimate hours of physical activity per day.

#### *Blood pressure*

Seated systolic and diastolic BP (mmHg) was measured by a registered nurse using a standard sphygmomanometer (Baumanometer® Desk Model, Copiague, NY, U.S.). Two BP measurements were recorded with a 2- to 3-minute rest period between readings; values were averaged.

#### *Sample collection*

Venous blood samples were obtained by a registered nurse between the hours 0700-0930 after a 12-hour fast. Samples were centrifuged at  $810 \times P$  for 12 minutes, after clotting. Serum was pipetted into cryovials and stored at  $-80^{\circ}\text{C}$  until completion of bioassays.

#### *Metabolic profile including serum glucose, insulin and lipids*

Serum glucose (Kit #1070, Stanbio Labs, Boerne, TX, U.S.) was measured (mmol/L) using ultra-violet (UV) spectrophotometry (version 3.0, Simple Reads Software, Varian, Santa Clara, CA, U.S.), and serum insulin (Catalog #IS130D, CalBiotech, Spring Valley, CA, U.S.) was measured (pmol/L) using enzyme-linked immunosorbent assay (GEN5 version 1.10, Epoch, BioTek, Winooski, VT, U.S.). Insulin resistance was estimated by homeostasis model of assessment-insulin resistance (HOMA-IR) using the formula: fasting insulin concentration ( $\mu\text{IU/mL}$ )  $\times$  fasting glucose concentration (mg/dL)  $\times$  0.0555/22.5 [38].

Serum total cholesterol (mmol/L), HDL-C (mmol/L) and triacylglycerides (mmol/L) concentrations (Kits #1010, #0599, and #2100, respectively, Stanbio Labs) were measured using UV spectrophotometry (Varian). Low-density lipoprotein-cholesterol (LDL-C) was calculated using the equation:  $LDL-C = total\ cholesterol - HDL-C - (triacylglycerides/5)$  [39].

All serum samples were analyzed in duplicate. Intra-assay coefficients of variation (CVs) for glucose and insulin were 7.4 and 6.0%, respectively. Intra-assay CVs for serum total cholesterol, HDL-C and triacylglycerides were 6.0, 5.9 and 7.9%, respectively.

### *Statistical analyses*

Using BW change from baseline to week 18 as the primary outcome, 21 participants per group were required to detect a treatment difference with 80% power when using t-tests and a 2-sided type I error of 5%. Using data from the 60 women who completed baseline measurements, data were first analyzed using intention-to-treat model. The nine women who did not complete the study (i.e., non-completers) were included in intention-to-treat analyses by replacing missing data with the last available measurement value. A secondary efficacy analysis was conducted by including only the 51 women who completed the 18-week intervention.

Data are presented as means  $\pm$  SEM unless otherwise indicated. Differences between the two cohorts were analyzed using independent *t*-tests. Differences in characteristics at baseline between DC and NC groups and between study-completers and those who withdrew also were analyzed using independent *t*-tests.

Using intention-to-treat data, a  $2 \times 4$  ANOVA with repeated measures on the time factor was performed to assess differences in anthropometrics and BP measurements and metabolic indicators between DC and NC groups over four intervals. The interaction of group (Treatment) by interval (Time) also was assessed. Data were analyzed using the Statistical Package for the Social Sciences (version 17.0, 2008, SPSS Inc., Chicago, IL, U.S.). All tests were two-sided with significance set at  $P < 0.05$ .

## **RESULTS**

Statistically significant differences were not observed between the two cohorts of women (July-December, March-July) in baseline characteristics or estimated dietary intakes, with the exception of self-reported physical activity. Therefore, data from both cohorts were combined and used in analyses. Sixty women (one Native American, two African American and 57 Caucasian), with a mean  $\pm$  SEM age of  $35.9 \pm 0.8$  years and BMI of  $31.0 \pm 0.6$  kg/m<sup>2</sup> began the intervention. Fifty-one of the women (85%) completed the intervention with no difference between DC and NC groups in discontinuation rate. No statistically significant differences in race, age, height, BW, BMI, waist and hip circumferences and physical activity between the DC (n = 30) and NC (n = 30) groups were found at baseline. There were no differences in these same characteristics at baseline for women randomly assigned to DC or NC group who completed (n = 51) the study compared to those who withdrew (n = 9).

#### *Snack compliance and class attendance*

Snack and beverage compliance was 90 and 90%, respectively, for the DC group and 92 and 94%, respectively, for the NC group. Attendance at nutrition education classes was 74 and 75% for the DC group and NC group, respectively. Neither snack and beverage compliance nor class attendance differed between groups.

#### *Intention-to-treat analysis*

##### *Dietary intake assessment*

Fifty-nine women completed 4-day food records at baseline. Table 3.1 displays estimated dietary intake of these participants at baseline and week 18 and changes over time. Within the DC and NC groups, women decreased estimated total energy, total sugar, saturated fat and cholesterol intakes, supporting that participants were successful in complying with energy restriction. Women in the DC group also reduced estimated sodium intake, and women in the NC group increased estimated dietary protein intake. Significant differences in estimated dietary intake variables were not found between groups at baseline and week 18 or in changes in nutrient intakes over time.



### *Anthropometric measurements*

Women in the DC group lost 5.3% ( $P < 0.001$ ) of BW, while women in the NC group lost 5.9% ( $P < 0.001$ ) of BW from baseline to week 18 (Table 3.1). The rate of BW change over time did not differ between groups. Women within both groups significantly reduced BMI, waist and hip circumferences and BF% over time (Table 3.2), again suggesting compliance with energy restriction. Changes in these anthropometric measurements did not differ between groups at any interval or over time.

### *Physical activity*

Self-reported physical activity (hr/day) was greater in the first cohort of women compared to second cohort ( $P < 0.01$ ) at baseline. Therefore, a physical activity change variable was created for each treatment group- (DC and NC) by-cohort (1 and 2). The change variable was then compared among these four groups using ANOVA. No significant difference in the change in physical activity from baseline to week 18 among treatment group-by-cohort was observed. The effect of time on physical activity was assessed within each group using repeated measures ANOVA. Self-reported physical activity did not differ within the four treatment group-by-cohort categories or between treatment groups over time.

### *Blood pressure*

From baseline to week 18, women in both DC and NC groups experienced significant reductions in systolic and diastolic BP (Table 3.3). For women in the DC group, the significant change in diastolic BP occurred by week 12. For women in the NC group, significant changes in systolic and diastolic BP occurred by week 12. Differences in BP measurements between groups were not found, and the changes within DC and NC groups over time were not different between groups.

### *Metabolic profile*

Women in the DC group had decreases in serum glucose concentration by week 6 (7.5% ↓,  $P < 0.001$ ), and at week 12 (5.3% ↓,  $P < 0.01$ ) and week 18 (12.9% ↓,  $P < 0.001$ ) compared

to baseline (Table 3.3). Women in the NC group also experienced decreases in serum glucose by week 6 (4.9% ↓,  $P < 0.05$ ), at week 12 (4.0% ↓,  $P < 0.05$ ) and week 18 (15.2% ↓,  $P < 0.001$ ) compared to baseline. Serum glucose concentrations did not differ between groups at any interval, and the change over time within each group did not differ between groups.

Serum insulin concentration decreased in the DC group (26.4% ↓,  $P < 0.01$ ) and in the NC group (26.8% ↓,  $P < 0.01$ ) from baseline to week 18 (Table 3.3). Differences between groups at any interval or for the change over time between groups in serum insulin were not statistically significant. HOMA-IR followed a pattern similar to serum insulin for both DC and NC groups.

Serum lipid concentrations did not differ between groups at any interval (Table 3.3). In the DC group, serum total and LDL-C increased by week 12 but returned to baseline levels at week 18. HDL-C decreased by week 6 but returned to baseline level at week 18 for women in the DC group. Women in the NC group had an increase in serum total cholesterol from baseline that persisted to week 18 (8.5% ↑,  $P < 0.05$ ). Women in the NC group also had a decrease in HDL-C from baseline to week 6 (9.5% ↓,  $P < 0.001$ ) that returned to baseline level at week 18. Changes over time in serum lipids were not different between DC and NC groups.

### *Efficacy analysis*

#### *Dietary intake assessment*

For those participants who completed the study ( $n = 51$ ), women in the DC ( $n = 26$ ) and NC ( $n = 25$ ) groups reduced estimated energy intake by 1,900 kJ/day ( $P < 0.001$ ) and 2,213 kJ/day ( $P < 0.001$ ), respectively. Macronutrient intake did not change in the DC group, while percent of energy from protein increased for women in the NC group ( $P < 0.01$ ). Changes in total sugar, fiber, saturated fat, cholesterol and sodium intakes within and between groups over time were similar to results previously reported using the intention-to-treat analysis.

#### *Anthropometric and blood pressure measurements and metabolic profile*

Due to the low number of dropouts from each group, changes in anthropometric and BP measurements and glucose, insulin, HOMA-IR and lipid concentrations in the efficacy analysis

were greater but had similar statistical significance to changes observed in intention-to-treat analysis. From baseline to week 18, BW decreased by  $5.1 \pm 1.4$  kg ( $P < 0.001$ ) and  $5.9 \pm 0.9$  kg ( $P < 0.001$ ) in the DC group and NC group, respectively. In the DC group, BMI, waist circumference, hip circumference and BF% decreased by  $1.9 \pm 0.2$  kg/m<sup>2</sup> ( $P < 0.001$ ),  $5.8 \pm 0.9$  cm ( $P < 0.001$ ),  $6.0 \pm 0.7$  cm ( $P < 0.001$ ) and  $3.7 \pm 0.4\%$  ( $P < 0.001$ ), respectively, from baseline to week 18. In the NC group, BMI, waist circumference, hip circumference and BF% decreased by  $2.2 \pm 0.3$  kg/m<sup>2</sup> ( $P < 0.001$ ),  $6.1 \pm 1.0$  cm ( $P < 0.001$ ),  $5.8 \pm 0.7$  cm ( $P < 0.001$ ) and  $3.3 \pm 0.6\%$  ( $P < 0.001$ ), respectively, from baseline to week 18. These changes over time were not significantly different between DC and NC groups.

Systolic and diastolic BP, respectively, decreased by  $3.6 \pm 1.4$  mmHg ( $P < 0.05$ ) and  $3.5 \pm 1.1$  mmHg ( $P < 0.05$ ) and by  $4.3 \pm 1.1$  mmHg ( $P < 0.01$ ) and  $5.3 \pm 1.4$  mmHg ( $P < 0.01$ ) in the DC group and NC group, respectively, from baseline to week 18. Serum glucose and insulin concentrations and HOMA-IR, respectively, decreased by  $14.7\%$  ( $P < 0.001$ ),  $30.6\%$  ( $P < 0.01$ ) and  $40.2\%$  ( $P < 0.001$ ) and by  $17.9\%$  ( $P < 0.001$ ),  $28.2\%$  ( $P < 0.05$ ) and  $39.6\%$  ( $P < 0.001$ ) in the DC group and NC group, respectively, from baseline to week 18. Values for serum lipid concentrations for participants who completed the study by DC or NC group were within 15% of values for intention-to-treat analysis. Changes over time in BP measurements and metabolic biomarkers did not differ between groups.

## DISCUSSION

Premenopausal women with overweight/obesity who followed an 18-week ERD that included twice daily dark chocolate or non-chocolate sweet snacks plus once daily sugar-free beverage were able to achieve an energy deficit, reduce BW and significantly improve BP and glucose and insulin concentrations. Participants in both groups were compliant with snack and beverage intake, as well as reducing overall energy intake as evidenced by improvements in BW and other anthropometric measurements. Although the hypothesis was not supported, and differential effects between the DC group and NC group were not found in this randomized comparative study, the two snack and beverage assignments were equally effective in promoting significant BW loss and improvements in metabolic parameters while following a

dietary approach that did not appreciably alter macronutrient composition of the habitual diet or completely eliminate sweet snacks. Because the current study did not include a non-snack and non-beverage control group, further evaluation is needed.

Golomb et al. [14] found an inverse relationship between frequency of chocolate consumption and BMI among nearly 1,000 adults, ages 20 to 85 years, even after adjusting for age, gender, physical activity, dietary components and energy intake. Using National Health and Nutrition Examination Survey, 1999-2004, data, O'Neil et al. [13] reported that chocolate consumers had significantly lower BW and waist circumference compared to non-consumers. Conversely, a prospective analysis by Greenberg and Buijsse [40] found more frequent consumption of chocolate to be significantly associated with greater weight gain over the long term. These epidemiological studies cannot draw causal inferences regarding effects of chocolate intake on BW or BMI but rather provide direction for future research to confirm these results. Further, these studies rely on self-reported data and not all distinguished the type of chocolate consumed. Randomized clinical trials exploring the impact of dark chocolate and cocoa on anthropometric measurements as the primary outcome measure are few; however, Desch et al. [41] observed a slight weight gain after three months of consuming 25 g of dark chocolate per day. Conversely, Taubert et al. [18] did not detect a change in BW after 18 weeks of daily consumption of 6.3 g of dark chocolate.

In an experimental study, Matsui et al. [42] demonstrated that cocoa intake for three weeks led to lower BW and white adipose tissue weight in male Wistar rats fed a high-fat diet compared to rats fed mimetic cocoa and high-fat diet. Cocoa consumption in these animals suppressed fatty acid synthase and other liver enzymes required for fatty acid synthesis. In addition, fatty acid binding protein and fatty acid synthase were lowered in white adipose tissue of cocoa-fed rats, suggesting altered lipid metabolism with cocoa intake in the presence of high dietary fat (-50% of total energy) [42]. Min et al. [43] cultured 3T3-L1 preadipocytes with cocoa polyphenol extract and found that signaling systems for cell proliferation were blunted. In a complementary 5-week whole animal study, Min et al. [43] further showed that C57BL/6N mice fed a high-fat diet and cocoa polyphenol extract had lesser BW gain and adiposity compared to mice fed only the high-fat diet. These experimental studies suggest biologically

plausible mechanisms by which cocoa may moderate BW and FM. Results of the current comparative trial are somewhat inconsistent with human epidemiologic and clinical trials [13,14,18,40,41], experimental animal [42,43] and cell culture [43] studies, in that women in the NC group also experienced benefits to BW and BF%. Discordant results are likely due to the design of the current study conducted in free-living women, where the total diet was not controlled and the lack of a control group. Nonetheless significant BW loss and improved BF% was achieved by incorporating preferred sweet snacks within an ERD.

Effects on BP, glucose, insulin, HOMA-IR, total cholesterol, HDL-C, triacylglycerides and LDL-C did not differ between the DC group and NC group. Several meta-analyses have indicated that consumption of 500 to 1,000 mg of cocoa flavanols per day results in acute (i.e., 2 to 12 weeks, with one 18-week trial) health benefits, including lowering of SBP [21,22,28] and DBP [21,24,28] as well as moderating insulin [24], HOMA-IR [22,24], total cholesterol [44] and LDL-C [22,24,44] and improving HDL-C [22,24], although one meta-analysis did not find any consistent effects on HDL-C [44]. One systematic review has reported no effect of cocoa intake on total cholesterol [22], and two reviews have indicated a lack of effect of cocoa on triacylglycerides [22,44]. Changes in the DC group were consistent with previous findings for SBP (-2.77 mmHg) [21] and DBP (-2.20 mmHg) [21], although mean differences for SBP and DBP were slightly better in the NC group. The change in HOMA-IR for the DC group was similar to the finding (-0.67) reported in the meta-analysis by Hooper et al. [24]. Although these benefits also were apparent for women in the NC group, the flavanol dosage for the DC group (270 mg) was less than the 500 to 1,000 mg used in previous studies. Blood lipids did not change or changed in expected directions when compared to other studies [16,20,45]. BW reduction has been shown to produce favorable changes in metabolic risk factors for disease [46,47]. Therefore, the weight loss achieved by women in the DC group may have overshadowed any differential effect or potentially additive effect of dark chocolate and cocoa intake on metabolic markers, given that comparable BW loss occurred in the NC group with similar metabolic outcomes.

This study is limited to premenopausal women of specific age and BMI ranges and cannot be generalized to others. The duration of 18 weeks was shorter than the ideal length of  $\geq 24$  weeks for a short-term weight-loss study; however, 18 weeks was of sufficient duration to

detect glucose, insulin and blood lipid changes measured in the current study and this duration was consistent or longer than previous trials examining dark chocolate and cocoa. Nutrition education classes included in the current intervention make it difficult to distinguish between positive outcomes attributed to weekly visits with a registered dietitian from benefits of dietary components. The current study was not a metabolic feeding trial and consequently relied on self-reported dietary intakes that have previously been shown to be underreported in overweight/obese individuals [48]. The current intervention was conducted with free-living women to mimic a real world scenario, and positive changes in BW, FM and metabolic markers demonstrated compliance with the dietary intervention, including energy restriction. Long-term intervention studies are needed, and future studies should compare inclusion of cocoa-based sweet snacks and sugar-free cocoa beverages into an ERD against a control ERD that does not include snacks or beverages to make appropriate recommendations for weight management programs. While the lack of a control group limits the generalizability of results, the design of the current study was to compare a sweet, widely consumed snack to one that is not as widely consumed. However, future interventions should compare an ERD that includes sweet snacks and beverages as well as sugar-free snacks and beverages to an ERD that does not.

While emerging evidence from animal, human and *in vitro* studies suggests dark chocolate and cocoa may have beneficial effects on body weight and other anthropometric measures [30], the current study found that an 18-week ERD that included twice daily dark chocolate snacks plus once daily sugar-free cocoa beverage resulted in a magnitude of BW loss and changes in BP and metabolic markers that were comparable to an ERD that included a sweet snack without dark chocolate or cocoa and sugar-free cocoa-free beverage. Premenopausal women with overweight/obesity and without established hypertension or hyperglycemia may experience clinically significant improvements in BP and glucose and insulin concentrations with a moderate 6.5% decrease in BW facilitated by an ERD that includes two energy- and portion-controlled sweet snacks and one sugar-free beverage daily. Portion- and energy-controlled sweet snacks, including dark chocolate or non-chocolate snacks, may be included in diets intended for BW modification.

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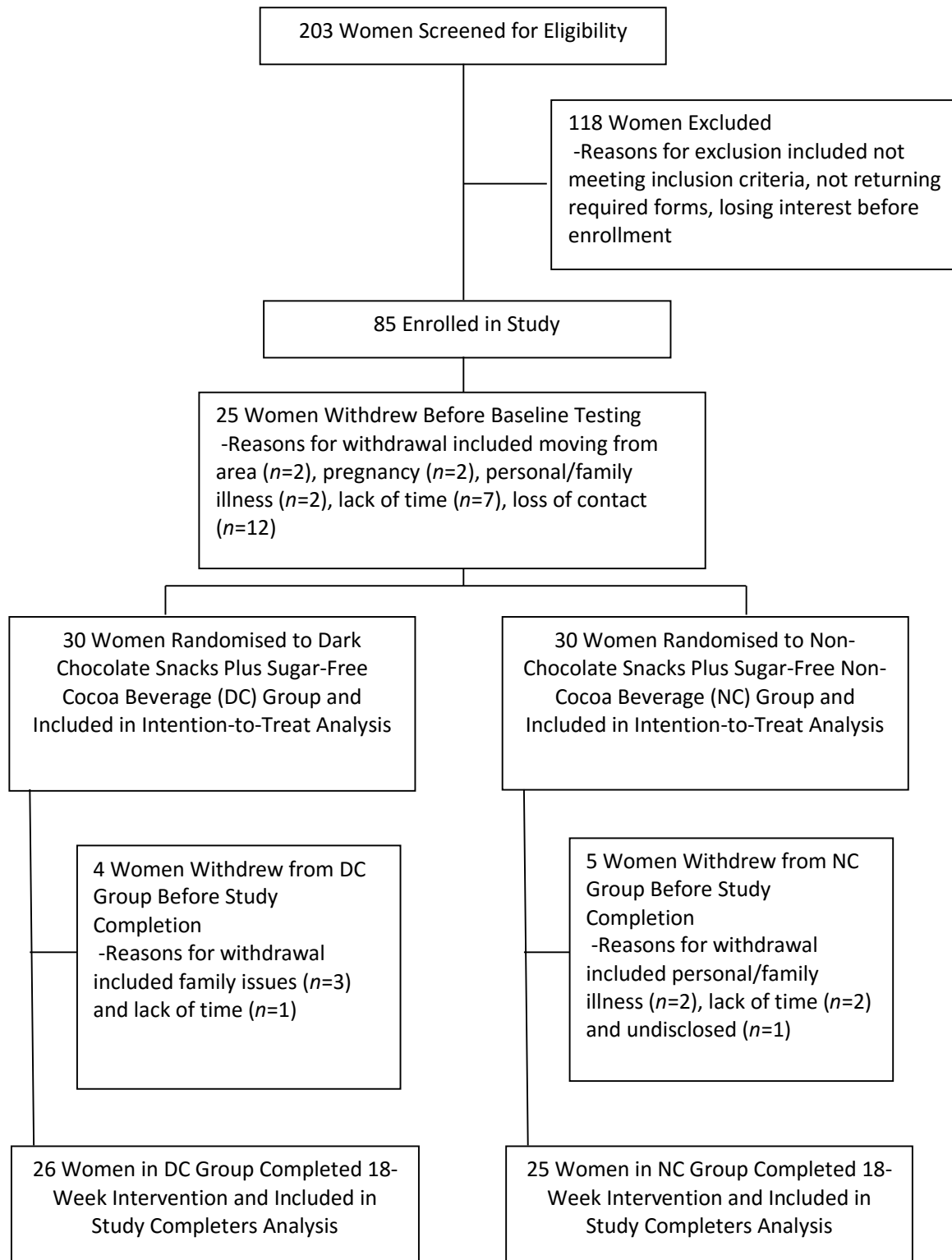
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**Figure 3.1.** Flow diagram of participant enrollment in a study of premenopausal women with overweight/obesity, designed to evaluate changes in body weight, blood pressure and selected metabolic biomarkers with an energy-restricted diet including twice daily dark chocolate snacks plus once daily sugar-free cocoa beverage or twice daily non-chocolate snacks plus once daily sugar-free non-cocoa beverage.

**Table 3.1.** Estimated dietary intake of premenopausal women with overweight/obesity at baseline, week 18 and change over time in a study evaluating changes in body weight, blood pressure and selected metabolic biomarkers with an energy-restricted diet including twice daily dark chocolate snacks plus once daily sugar-free cocoa beverage or twice daily non-chocolate snacks plus once daily sugar-free non-cocoa beverage

Dietary variable	Interval	Dark-chocolate snacks plus sugar-free cocoa beverage group ( $n=29$ ) <sup>1)</sup>	Non-chocolate snacks plus sugar-free non-cocoa beverage group ( $n=30$ )
Total energy intake (kJ/d)	Baseline Week 18 Change	8473 ± 348 <sup>2)</sup> 6887 ± 275 1586 ± 348***	8807 ± 406 <sup>2)</sup> 6979 ± 302 1828 ± 360***
Carbohydrate intake (% of total energy)	Baseline Week 18 Change	49.1 ± 1.7 48.5 ± 0.8 -0.6 ± 1.7	50.5 ± 1.4 50.7 ± 1.4 +0.2 ± 1.1
Fat intake (% of total energy)	Baseline Week 18 Change	34.7 ± 1.1 33.8 ± 1.0 -0.9 ± 1.1	33.1 ± 1.2 31.5 ± 1.4 -1.6 ± 1.1
Protein intake (% of total energy)	Baseline Week 18 Change	15.8 ± 0.5 16.2 ± 0.5 +0.4 ± 0.4	14.9 ± 0.4 16.5 ± 0.6 +1.6 ± 0.5**
Alcohol intake (% of total energy)	Baseline Week 18 Change	1.3 ± 0.4 1.5 ± 0.6 +0.2 ± 0.5	1.5 ± 0.7 1.2 ± 0.5 -0.3 ± 0.7
Total sugar (g/d)	Baseline Week 18 Change	84.4 ± 6.1 70.9 ± 4.0 -13.5 ± 5.9*	103.9 ± 8.2 75.4 ± 4.8 -28.5 ± 8.3*
Total fibre (g/d)	Baseline Week 18 Change	21.2 ± 1.9 19.6 ± 1.3 -1.8 ± 2.3	18.9 ± 1.3 18.3 ± 1.0 -0.6 ± 1.3
Saturated fat (g/d)	Baseline Week 18 Change	25.2 ± 1.5 19.2 ± 1.4 -6.0 ± 1.7***	27.3 ± 2.0 20.3 ± 1.8 -7.0 ± 2.1**
Cholesterol (mg/d)	Baseline Week 18 Change	257 ± 21 181 ± 15 -76 ± 23**	235 ± 18 184 ± 16 -51 ± 18**
Sodium (mg/d)	Baseline Week 18 Change	3407 ± 174 2928 ± 152 -479 ± 181*	3520 ± 235 3174 ± 171 -346 ± 215

<sup>1)</sup>Missing data for  $n = 1$  participant.

<sup>2)</sup>Values are means ± SEM.  $P$ -values from intention-to-treat analysis, using analysis of covariance with repeated measures on the time factor.

\* $P < 0.05$ , \*\* $P < 0.01$ , \*\*\* $P < 0.001$  within group change from baseline. There were no significant differences in estimated dietary intake variables between snack/beverage groups at any interval or for the change over time between snack/beverage groups.

**Table 3.2.** Anthropometric measurements of premenopausal women with overweight/obesity at baseline and change from baseline at weeks 6, 12 and 18 in a study evaluating changes in body weight, blood pressure and selected metabolic biomarkers with an energy-restricted diet including twice daily dark chocolate snacks plus once daily sugar-free cocoa beverage or twice daily non-chocolate snacks plus once daily sugar-free non-cocoa beverage

Measurement	Interval	Dark-chocolate snacks plus sugar-free cocoa beverage group (n=30)	Non-chocolate snacks plus sugar-free non-cocoa beverage group (n=30)
Age (y)	Baseline	36.0 ± 1.1 <sup>1)</sup>	35.9 ± 1.1 <sup>1)</sup>
Height (cm)	Baseline	164.9 ± 0.8	164.9 ± 1.2
Weight (kg)	Baseline	83.7 ± 2.5	85.1 ± 2.3
	Week 6	-2.7 ± 0.4***	-2.6 ± 0.4***
	Week 12	-4.2 ± 0.5***	-4.0 ± 0.7***
	Week 18	-4.4 ± 0.6***	-5.0 ± 0.9***
Body mass index (kg/m <sup>2</sup> )	Baseline	30.8 ± 0.9	31.2 ± 0.7
	Week 6	-1.0 ± 0.1***	-1.0 ± 0.2***
	Week 12	-1.6 ± 0.2***	-1.5 ± 0.2***
	Week 18	-1.6 ± 0.2***	-1.8 ± 0.3**
Waist circumference (cm)	Baseline	89.4 ± 1.9	92.0 ± 1.9
	Week 6	-3.0 ± 0.4***	-3.4 ± 0.6***
	Week 12	-4.2 ± 0.5***	-4.8 ± 0.7***
	Week 18	-5.0 ± 0.9***	-5.1 ± 1.0***
Hip circumference (cm)	Baseline	115.4 ± 1.8	116.4 ± 1.6
	Week 6	-3.9 ± 0.5***	-3.6 ± 0.6***
	Week 12	-4.7 ± 0.7***	-4.7 ± 0.7***
	Week 18	-5.2 ± 0.8***	-4.8 ± 0.8***
Body fat (%)	Baseline	40.4 ± 1.0	41.2 ± 1.0
	Week 6	-1.4 ± 0.2***	-1.0 ± 0.3***
	Week 12	-2.7 ± 0.4***	-2.1 ± 0.4***
	Week 18	-3.2 ± 0.5***	-2.7 ± 0.6***

<sup>1)</sup>Values are means ± SEM for baseline values and mean ± SEM for change from baseline values. *P*-values from intention-to-treat analysis, using analysis of covariance with repeated measures on the time factor.

\**P* < 0.05, \*\**P* < 0.01, \*\*\**P* < 0.001 within group change from baseline. There were no significant differences in measurements between snack/beverage groups at any interval or for the change over time between snack/beverage groups.

**Table 3.3.** Blood pressure measurements and selected metabolic biomarkers of premenopausal women with overweight/obesity at baseline and change from baseline at weeks 6, 12 and 18 in a study evaluating changes in body weight, blood pressure and selected metabolic biomarkers with an energy-restricted diet including twice daily dark chocolate snacks plus once daily sugar-free cocoa beverage or twice daily non-chocolate snacks plus once daily sugar-free non-cocoa beverage

Measurement	Interval	Dark-chocolate snacks plus sugar-free cocoa beverage group (n=30)	Non-chocolate snacks plus sugar-free non-cocoa beverage group (n=30)
Systolic blood pressure (mm Hg)	Baseline	118.8 ± 1.4 <sup>1)</sup>	119.7 ± 1.7 <sup>1)</sup>
	Week 6	-1.7 ± 1.0	-2.0 ± 1.2
	Week 12	-0.6 ± 1.0	-1.8 ± 0.8*
	Week 18	-2.7 ± 1.2*	-3.4 ± 1.0**
Diastolic blood pressure (mm Hg)	Baseline	72.8 ± 1.4	74.9 ± 1.4
	Week 6	-1.6 ± 0.9	-1.6 ± 1.3
	Week 12	-2.2 ± 1.0*	-2.7 ± 1.2*
	Week 18	-2.7 ± 1.0**	-4.2 ± 1.3**
Glucose (mmol/L)	Baseline	5.58 ± 0.11	5.44 ± 0.10
	Week 6	-0.42 ± 0.12***	-0.27 ± 0.11*
	Week 12	-0.29 ± 0.08**	-0.22 ± 0.09*
	Week 18	-0.72 ± 0.13***	-0.83 ± 0.12***
Insulin (pmol/L)	Baseline	50.00 ± 5.33	49.31 ± 5.20
	Week 6	+2.78 ± 8.75	-1.39 ± 3.30
	Week 12	-6.95 ± 3.81	-2.78 ± 4.06
	Week 18	-13.20 ± 4.06**	-13.20 ± 4.56**
Homeostasis model of assessment – insulin resistance	Baseline	1.80 ± 0.21	1.71 ± 1.01
	Week 6	+0.04 ± 0.38	-0.08 ± 0.72
	Week 12	-0.33 ± 0.16	-0.13 ± 0.78
	Week 18	-0.63 ± 0.15***	-0.62 ± 0.88***
Total cholesterol (mmol/L)	Baseline	4.10 ± 0.21	4.15 ± 1.17
	Week 6	-0.16 ± 0.08	-0.05 ± 0.56
	Week 12	+0.19 ± 0.08*	+0.04 ± 0.61
	Week 18	+0.12 ± 0.09	+0.35 ± 0.59*
High-density lipoprotein-cholesterol (mmol/L)	Baseline	1.33 ± 0.05	1.29 ± 0.05
	Week 6	-0.08 ± 0.03*	-0.12 ± 0.03***
	Week 12	-0.04 ± 0.02*	-0.05 ± 0.03
	Week 18	+0.04 ± 0.03	+0.05 ± 0.03
Low-density lipoprotein-cholesterol (mmol/L)	Baseline	2.43 ± 0.11	2.49 ± 0.20
	Week 6	-0.11 ± 0.08	+0.08 ± 0.11
	Week 12	+0.21 ± 0.07*	+0.05 ± 0.11
	Week 18	+0.04 ± 0.10	+0.23 ± 0.12
Triacylglycerides (mmol/L)	Baseline	0.73 ± 0.04	0.82 ± 0.07
	Week 6	+0.06 ± 0.07	-0.02 ± 0.05
	Week 12	+0.06 ± 0.05	+0.06 ± 0.05
	Week 18	+0.05 ± 0.07	+0.06 ± 0.10

<sup>1)</sup>Values are means ± SEM for baseline values and mean ± SEM for change from baseline values. *P*-values from intention-to-treat analysis, using analysis of covariance with repeated measures on the time factor.

\**P* < 0.05, \*\**P* < 0.01, \*\*\**P* < 0.001 within group change from baseline. There were no significant differences in measurements between snack/beverage groups at any interval or for the change over time between snack/beverage groups. Homeostasis model of assessment-insulin resistance calculated by fasting insulin concentration (μIU/mL) × fasting glucose concentration (mg/dL) × 0.0555/22.5.



## Facilitators and barriers to weight loss and weight loss maintenance: a qualitative exploration<sup>2</sup>

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### Abstract

**Background:** The present study aimed to explore facilitators and barriers to weight loss (WL) and weight loss maintenance (WLM) in women who participated in a primary, 18-week comparative trial that promoted WL with an energy-restricted diet.

**Methods:** Twenty-three women participated in seven focus groups conducted by a moderator and co-facilitator using open-ended questions and probes. Focus groups were held in a private room and audio tape-recorded. Tapes were transcribed verbatim and thematic analysis was used to evaluate transcripts for common themes.

**Results:** Accountability to others, social support, planning ahead, awareness and mindfulness of food choices, basic nutrition education, portion control, exercise, and self-motivation were perceived as key facilitators for WL and WLM by women. Identified barriers included life transitions, health status changes, internal factors, environmental pressures, lack of accountability and an absence of social support.

**Conclusions:** Future interventions should address these salient facilitators and barriers to promote sustainable changes in women across their WL and WLM journeys.

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## Introduction

Following weight loss (WL) success, weight loss maintenance (WLM) remains a challenge (Stunkard & McLaren-Hume, 1959; Lyznicki et al., 2001; Stevens et al., 2006). Dietary programmes and related interventions that produce WL in the short term rarely promote WLM over the long term (Jeffery et al., 2000). Indeed, approximately half of any weight lost is regained within 1 year, and most individuals return to their baseline weight within 3–5 years (Goodrick et al., 1996; Jeffery et al., 2000; Byrne et al., 2003).

Although interventions and programmes provide strategies for short-term WL, few include WLM strategies, which may differ from those used to achieve WL (Byrne et al., 2003; Reyes et al., 2012). Additionally, studies examining effective long-term WL strategies (Klem et al., 1997; Jeffery et al., 2000; Ogden, 2000; Elfhag & Rossner, 2005; Wing & Phelan, 2005; Wing et al., 2006; Svetkey et al., 2008; Burke et al., 2011) have not always captured the subtleties of WLM that can only be uniquely described by individuals engaging in such efforts (Kayman et al., 1990; Byrne et al., 2003; Barnes et al., 2007; Reyes et al., 2012). The National Weight Control Registry, with over 10 000 members, is the largest database of individuals successful at long-term WLM (Wing & Phelan, 2005). To be eligible to join the National Weight Control Registry, individuals must have maintained a WL of  $\geq 13.6$  kg ( $\geq 30$  lbs) for  $\geq 1$  year. Behavioural and psychological characteristics as well as WLM strategies of National Weight Control Registry members have been prospectively investigated using detailed questionnaires and follow-up surveys. Six key strategies for WLM have been identified and include: engaging in high levels of physical activity; consuming a diet low in energy and fat; eating breakfast; maintaining a consistent eating pattern; self-monitoring of weight on a frequent basis; and reversing slight weight regains quickly (Wing & Phelan, 2005). These behaviours do not fully reflect the cognitive and emotional aspects of WLM strategies or real and perceived structural support systems that influence WLM success. Additionally, National Weight Control Registry members each have their own WL journey to long-term WLM. Strategies for and barriers and facilitators to WL and WLM need to be examined further in groups of individuals who have undergone the same WL intervention.

The purpose of the present qualitative study was to use focus groups to explore facilitators and barriers to WL and WLM in women who previously participated in a randomised comparative trial that promoted WL using an energy-restricted diet (Nickols-Richardson et al., 2014) and to capture insights into their perceptions regarding WL during and WLM following completion of a single intervention. No hypotheses were established a priori because an inductive approach was used to analyse data.

## **Materials and methods**

### **Participants**

Women were recruited from a pool of 51 participants who completed an 18-week comparative trial that promoted WL using an energy-restricted diet including portion-controlled daily sweet snacks; diets were identical in macronutrient composition, differing only in snack group assignment (Nickols-Richardson et al., 2014). The primary intervention included a nutrition education component delivered by a registered dietitian. Interactive, group education classes were held for 1 h each week during the 18-week trial and included strategies for portion control, planning ahead for meals and consuming vegetables for WL (Nickols-Richardson et al., 2014). Class topics included general nutrition principles, eating away from home, food selection, preparation methods and recipe modification.

All women who fully completed the primary study ( $n = 51$ ) were invited to participate in the present qualitative study to obtain a homogenous sample of individuals with similar backgrounds and experiences related to WL (Morse & Field, 1995; Stewart et al., 2007; Krueger & Casey, 2009; James et al., 2012), with no additional inclusion or exclusion criteria. Original inclusion and exclusion criteria are described elsewhere (Nickols-Richardson et al., 2014). Briefly, the primary study included overweight and obese women who were moderately physically active, eumenorrheic, with a self-reported stable body weight, who scored  $<50$  on the Zung Self-Rating Depression Scale/Status Inventory (Zung, 1986) and who reported no intolerance, aversion or allergy to chocolate. Women who currently smoked, were pregnant or attempting to become pregnant, had a hysterectomy and/or ovariectomy without hormone replacement therapy and those who used oral contraceptives for  $<2$  years in duration (if used)

were excluded, in addition to women who used medications, including steroid or thyroid hormones, bisphosphonates, anticonvulsants and glucocorticoids, or consumed  $\geq 40$  g of chocolate per day (i.e. the equivalent of one standard chocolate bar or more day<sup>-1</sup>).

Packets explaining the purpose of the present study were sent to women, followed by telephone or e-mail messages confirming the receipt of study materials. By completing and returning study questionnaires, participants provided their implied informed consent for the study, and interested women were invited to participate in one focus group session.

Recruitment, enrollment activities and focus group sessions were conducted from 16 April until 9 July 2012, approximately  $\geq 20$  months following the completion of the primary intervention.

The present study and primary study were approved by the Institutional Review Board for Research Involving Human Subjects at The Pennsylvania State University.

### **Anthropometric measurements**

On the day of the focus group session, standing height was measured to the nearest 0.1 cm using a stadiometer (Seca 700; Seca North America East, Hanover, MD, USA) and body weight was measured to the nearest 0.1 kg using a calibrated balance-beam scale (Seca 700). Height and body weight were used to calculate body mass index (BMI;  $\text{kg m}^{-2}$ ). A retractable measuring tape (Gulik II; Country Technology, Inc., Gay Mills, WI, USA) was used to measure waist and hip circumferences to the nearest 0.1 cm. Two measurements at both the waist and the hip were obtained and averaged to result in a single measurement for each site. Waist circumference was measured at the narrowest point of the waist, approximately 1 inch (2.54 cm) above the navel; hip circumference was measured at the widest part of the buttocks (Nickols-Richardson et al., 2014). One investigator completed all height and body weight measurements; a second investigator conducted all waist and hip circumference measurements.

### **Focus group sessions**

Focus groups promoted discussion among participants and encouraged sharing of perceptions, experiences and opinions related to WL and WLM. As a result of a limited pool of participants, it

was preferable to conduct more groups with fewer participants, as recommended by Greenbaum (1998) and Krueger (1998) and employed by Reyes et al. (2012). Seven mini-focus groups, including dyads and one triad, were conducted (Greenbaum, 1998; Krueger, 1998; Krueger & Casey, 2009). Groups included four, three, two, four, four, four and two women per session. The same moderator (CJM), who was not involved in the primary intervention, guided participant discussions, according to standard focus group methods (Creswell, 1998; Stewart et al., 2007; Harris et al., 2009; Krueger & Casey, 2009). A purpose statement was read at the beginning of each focus group for consistency of context and orientation to discussion. Participants were asked to respond to 11 open-ended questions (Table 3.4) that were obtained from or modelled after those developed by Hindle & Carpenter (2011). Questions, including probing statements, covered topics including WL and WLM success and limitations, facilitators and barriers to WLM, strategies for weight regulation, eating patterns and perceptions of snacking. Questions also addressed constructs of the theory of planned behaviour, social cognitive theory and the health belief model (Table 3.4).

One co-facilitator (SNR) attended all focus groups and maintained written records. Focus groups were conducted in a private room and audio tape-recorded. Digital audiotapes were transcribed verbatim by the facilitator using written records from the co-facilitator to clarify and/or verify transcribed audiotapes as needed. Each focus group lasted approximately 1 h. Upon completion of the session, each participant received a \$50 gift card.

### **Statistical analysis**

Descriptive statistics [mean (SD)] were used to characterise study participants. Paired t-tests were used to compare current anthropometric measurements of women participating in focus groups (n = 23) with their post-primary-intervention measurements. Independent t-tests were used to compare current anthropometric measurements of women who participated in focus groups (n = 23) with post-primary-intervention measurements of women who did not participate in focus groups (n = 28). Quantitative data analyses were conducted using SPSS, version 20.0 (IBM Corp., Armonk, NY, USA).  $P < 0.05$  was considered statistically significant.

Focus group transcripts were evaluated using thematic analysis (Braun & Clarke, 2006). The moderator and co-facilitator independently reviewed transcripts and generated codes that were later collated into themes. To be considered, themes must have been stated by at least three participants across groups. Following independent analysis, themes were confirmed by these investigators through a question-by-question review of the major themes identified. Discrepancies were reconciled through discussion and further review of transcripts. As common themes were identified, the meanings of these phenomena were interpreted and considerations for future programmes were proposed. Selected verbatim quotes that captured participants' insights, perceptions and opinions have been included.

## **Results**

### **Subject characteristics**

Anthropometric measurements were obtained from twenty-three women, with a mean (SD) age of 38.8 (6.0) years and mean (SD) BMI of 30.0 (6.2) kg m<sup>-2</sup> who engaged in one of seven focus group sessions. Twelve women declined to participate, and 16 women were lost to follow-up after the primary study. Characteristics of participants are presented in Table 3.5. Twenty-one women were Caucasian and two women were African American. There were no significant differences in anthropometric measurements of focus group participants (n = 23) and women who did not participate (n = 28). Within focus group participants, BMI, waist circumference and hip circumference measurements were significantly lower after the 18-week primary intervention compared to current measurements, demonstrating that participants were not successful at WLM.

### **Theme identification and common themes**

Nine major themes were identified through data analyses and included: (i) the weight loss journey; (ii) accountability and support; (iii) planning ahead, mindfulness and awareness; (iv) nutrition education; (v) portion control; (vi) exercise; (vii) motivation; (viii) total lifestyle change; and (ix) eating patterns and snacking. The meanings of these themes and considerations for future interventions are summarised in Table 3.6.

Women described their WL journeys as continual bouts of weight gain, WL, WLM and prevention of weight regain that were related to life transitions. One woman stated, 'It's [WL journey] definitely going to be an ongoing process'. Another participant reflected that 'it has been this up and down type of journey for me, for a long time'. All women self-reported at least one attempt at losing weight throughout their lifetimes, with many women reporting multiple episodes and methods for WL. Specific methods used by participants included Weight Watchers®, The South Beach Diet®, over-the-counter medications and various energy-restricted diets. Although these approaches were successful in producing initial WL, reports of long-term success with WLM were scarce among these participants.

Accountability to others and support from friends, family members and coworkers were verbalised as key facilitators that allowed women to maintain or continue their WL following the intervention. Lack of accountability to someone else and an absence of support from others were commonly reported as barriers to achieving further WL and WLM following completion of the primary study. Compared to previous attempts with WL, accountability to study investigators was perceived as a key component of the WL intervention, motivating women to achieve WL. Women also identified weekly educational group meetings during the primary comparative trial as being useful for facilitating accountability, support and motivation. Without an individual (i.e. study investigator) monitoring their progress after the primary intervention ended, women perceived a drastic drop in motivation for WLM. One woman's statement ('I mean for me, hands down, accountability. I have no one looking over my shoulder') represented this idea. Women in the present study did not mention self-accountability, but only accountability to someone else.

Although some women perceived others to be supportive and complimentary of their WL efforts, many women reported negative reactions. Women indicated that friends, family members and coworkers tempted them with high-energy, savoury foods or made 'snide' remarks regarding their healthy food choices when eating in restaurants, at social gatherings and during family mealtimes. Comments such as: 'You look ill.'; 'You don't need to lose weight'; 'You are having a salad again today?'; 'I don't know why you have to eat all that [healthy] stuff, just eat less'; 'You should stop losing weight'; and 'Go ahead and eat that [dessert]. You deserve

that. You work hard' were reported. Several women remarked that their spouses hid and consumed snack foods and candies in secret. Women considered that such comments and practices were forms of sabotage that were often unintentional, yet unhelpful in facilitating WL and WLM. One participant expressed this concern by stating, 'See my support group means to be supportive, but comes off as not. Like my husband had made a comment one time. He's like, "Oh I hate when you're on a diet, because then I can't eat what I want"'. One woman stated, 'When you don't have the support group, it makes [WLM] very difficult'.

Planning ahead emerged as a common thread throughout focus group discussions. Although planning ahead was identified as a strategy that women used to maintain their WL, women also recognised that such preparation took a substantial amount of time. Women who planned their meals in advance or took their own food to social events perceived greater success with WL and WLM. For example, one woman stated, 'Plan. If you don't plan, it's ... uh ... for me, it's just so hard'. Planning was reported as particularly helpful for maintaining the dietary intervention during social activities, holidays, travel and when dining away from home. The terms 'mindfulness' and 'awareness' were commonly repeated by women during focus group discussions. These terms were often used in conjunction with planning ahead, as demonstrated by one woman who stated, 'And being planful and being mindful, like paying attention'. Another participant commented that 'You know, that sort of speaks to, like what you [other participant] were saying, like making healthier choices, just about what you're eating and recognising like where the calories come from and just really being a bit more mindful of that'.

Many women reported that the addition of weekly sessions with a 'credible resource' (registered dietitian) differed from past attempts to lose weight using commercial WL programmes and approaches. During focus group discussions, most women reported that they gained valuable nutrition knowledge and perceived an enhanced ability to make healthier food choices during the WL intervention. One woman stated, 'Yeah, for me, it was the accountability mixed with the, um, the education'. A majority of women admitted that they did not continue applying nutrition education principles during WLM because they no longer had the group support system. Women reported that weekly sessions assisted them with incorporating more



fruits and vegetables, whole grains, lean protein and low-fat dairy in their eating patterns by having a greater sense of awareness of nutritional value of foods and an understanding of the relationship between dietary intake and body weight changes. After the intervention, loss of this resource was a barrier to WLM, as expressed by one woman who noted, 'And having that educational background from those sessions just really helped me know what I have to do, it's just whether or not I'm following it on that day [after the trial]'

Many women in the present study indicated that they became acutely aware of their own 'portion distortion' during the WL trial. Furthermore, some women reported having an 'inner voice' reminding them to avoid large portion sizes in the interval between the end of the intervention and focus group session. One woman stated, 'I kept hearing 'that's portion distortion, that's portion distortion' in my mind'. Another participant commented, 'I think measuring my cereal in the mornings is a big eye opener'. Women perceived that, when they implemented portion control during social events, holidays and dining away from home, they were better able to maintain WL. Portion control was identified as the key facilitator to body weight regulation by many women during the focus group sessions.

Women who perceived greater success with additional WL and WLM post-intervention reported developing an exercise routine and continuously engaging in regular exercise. For example, one woman reported that, 'exercise for me is the key'. Another participant stated, 'I think my biggest thing, it's not what I'm eating or what I'm not eating, it's exercising'. Many women who self-reported an inability to maintain WL and subsequently experienced weight gain considered that a lack of exercise was a substantial barrier to their success. Finding 'time' and 'enjoyable activities' were cited as issues for not engaging in exercise, whereas other women expressed 'feeling guilty' about taking time for themselves to exercise.

Self-motivation or a lack thereof was an additional facilitator or barrier, respectively, to WL and WLM reported by women during focus group discussions. Other internal factors, including a lack of self-control, willpower and self-regulation, were identified as barriers. Readiness for change was perceived as necessary for self-motivation; one woman commented, 'Readiness. You have to be ready'. Waning self-motivation also was commonly cited as a barrier, as represented by one woman's comment, 'I have trouble maintaining focus and

motivation, even though I am successful in the beginning'. Renewing motivation on a daily basis was perceived by women as a facilitator to WL and WLM. Women referred to this as a 'fresh-slate mentality' or the ability to self-forgive 'slip-ups' or 'bad days' of poor compliance with healthy dietary patterns. This perception was expressed by a participant who stated, 'For me, the, the notion that each day is, is a new day instead of, oh well, yesterday was shot so I might as well continue the downward spiral. That has been helpful to say, okay, I'll start again today'.

Several women commented that a 'total lifestyle change', encompassing diet and exercise modifications, was required to achieve and maintain WL. One woman supported this idea by stating, 'Exercise, eating right. Just a better whole lifestyle'.

A distinct feature of the primary WL trial was the use of a dietary approach that emphasised vegetables and portion control, at the same time as including sweet snacks and a sugar-free beverage on a daily basis. Women reported that they found this approach 'quite flexible' and 'accommodating' for WL and WLM. Almost all of the women considered that inclusion of portion-controlled sweet snacks during the 18-week intervention altered their attitudes, beliefs and perceptions of eating and snacking patterns for the long term. One woman represented these feelings by stating, 'So I always thought it was bad to snack, and since, I realised that it's okay, and that it's actually easier for me to keep my weight in check if I snack'. During focus group discussions, women reported an overall improvement in eating patterns as a result of 'more frequent breakfast consumption,' 'better portion control' and 'healthy snack choices'. Women experienced a shift in their perceptions of snacks from 'non-nutritious', 'easily accessible food items' that were generally 'consumed without planning' and snack foods that were used to satisfy cravings ('vending machine food items') from snacks consumed to control or manage hunger and meet overall dietary intake recommendations ('fruits, vegetables, low-fat dairy foods'). For example, one woman stated, 'Snack foods and snacks are two different things. Snacks are – you can be purposeful about your snacks. Snack foods are the easy way out'. Most women expressed a positive view of snacks, considering that they are beneficial and necessary to dietary intake during WL and WLM.

## **Discussion**

Few qualitative studies examining facilitators and barriers to WL and WLM have been conducted (Byrne et al., 2003; Barnes et al., 2007; Befort et al., 2008; Herriot et al., 2008; Thomas et al., 2008; Ely et al., 2009; Green et al., 2009; Hardcastle & Hagger, 2011; Hindle & Carpenter, 2011; Reyes et al., 2012), specifically in a homogenous sample of individuals with similar experiences related to WL and WLM. Even so, many of the themes identified by women in the present study are consistent with strategies reported in previous qualitative and quantitative studies (Kayman et al., 1990; Klem et al., 1997; Jeffery et al., 2000; Ogden, 2000; Wing & Hill, 2001; Byrne et al., 2003; Elfhag & Rossner, 2005; Wing & Phelan, 2005; Wing et al., 2006; Barnes et al., 2007; Befort et al., 2008; Herriot et al., 2008; Svetkey et al., 2008; Thomas et al., 2008; Ely et al., 2009; Green et al., 2009; Hardcastle & Hagger, 2011; Hindle & Carpenter, 2011; Sciamanna et al., 2011; Reyes et al., 2012).

Approaches used to induce WL by women in the present study are consistent with those reported by others (Barnes et al., 2007; Herriot et al., 2008; Thomas et al., 2008; Hindle & Carpenter, 2011; Reyes et al., 2012) as are reports of multiple WL attempts throughout the lifetime (Hindle & Carpenter, 2011). Women in the present qualitative study specifically acknowledged certain points of the lifespan to be problematic and stressors that precipitated weight gain or made weight maintenance difficult throughout their weight management journeys. Specifically, women identified pregnancy and post-pregnancy years as particularly challenging times, consistent with a qualitative study of African American women in whom motherhood was cited as a precursor to weight gain (Befort et al., 2008) and the initiation of WL efforts as a result of this weight gain (Goodrick et al., 1996). Life transitions related to student status, employment, family structure and health status also were reported by women as critical periods that hindered weight management. Both young adulthood and midlife appear to be crucial intervals for weight gain (Ball et al., 2002; Wane et al., 2010), and life stress and significant life events also have been associated with weight gain (Elfhag & Rossner, 2005). Women perceived that their capacity for achieving and maintaining WL was lower than for men, consistent with evidence demonstrating that women are twice as likely as men to experience major weight gain over the life course (Williamson et al., 1990). Consistent with other studies, women described their desires to improve appearance, self-esteem and/or

health as motivations for losing body weight (Goodrick et al., 1996; Barnes et al., 2007; Thomas et al., 2008; Hindle & Carpenter, 2011; Reyes et al., 2012). Therefore, future interventions should be tailored to the individual needs of each participant with attention to a woman's biology, physiology, life stage and previous experiences.

Social support is widely regarded as an integral element of WL and WLM programmes, regardless of whether this support comes from friends, family members, coworkers or a support group (Elfhag & Rossner, 2005; Barnes et al., 2007). Additionally, social support has been identified as both a facilitator and barrier to making dietary and behaviour changes in previous research (Tessaro et al., 2006). Therefore, it is not surprising that women in the present qualitative study reported that support or a lack thereof from these individuals and groups served to facilitate or hinder WL and WLM, respectively. Saboteurs have been identified as a barrier to WLM in several studies (Befort et al., 2008; Thomas et al., 2008; Hardcastle & Hagger, 2011; Hindle & Carpenter, 2011), as also reported by women in the present study. Evidence suggests that social support may enhance motivation for weight loss (Jeffery et al., 2000), offering an explanation as to why women found social support so crucial. Previous research has identified group support as being critical to weight management as a means of problem-solving and experience sharing (Herriot et al., 2008; Ely et al., 2009), facets that were shared by participants in the present study. Unlike members of the National Weight Control Registry, women did not report self-accountability as a means for motivation but, instead, found external accountability necessary to provide motivation and support. Focus group participants in a previous study of WL maintainers and regainers (Reyes et al., 2012) perceived that a lack of external accountability and low levels of structured support resulted in decreased motivation for weight regulation. Similarly, Hardcastle & Hagger (2011) found that obese men and women desired an external source of accountability to serve as an incentive to maintain lifestyle changes and provide support and motivation. Internal factors appear to be key components for successful weight management in some (Herriot et al., 2008) and maintaining motivation appeared to be a struggle for many of the women in the present study. Sciamanna et al. (2011) found motivation to engage in weight control practices to diminish over time and suggested different practices should be encouraged throughout the weight management

process to maintain motivation and increase effectiveness. Along these lines, renewing motivation on a daily basis was perceived by women as a facilitator to WL and WLM, a finding supported by Green et al. (2009). Programmes and interventions that provide a source of external accountability, as well as a support network, may be beneficial in helping individuals achieve their WL and WLM goals.

The primary WL intervention emphasised planning for food intake, whereas previous WL interventions have not always included this skill (Wing et al., 2006; Svetkey et al., 2008; Foster-Schubert et al., 2012). Consequently, the theme of planning ahead and being mindful and aware of food choices has not been identified in previous qualitative work. A cross-sectional study of US adults who were successful at WLM did find that planning was a crucial component in their success (Sciamanna et al., 2011). Although the primary intervention did not employ mindful eating strategies, previous research has shown that a conscious awareness of foods and energy actually consumed plays a role in WL and WLM (Wansink, 2010). Future interventions should incorporate planning skills to help individuals enhance mindful awareness of food intake.

Women in the present study reported that they gained valuable general nutrition knowledge as a result of nutrition education classes and appreciated that a registered dietitian was involved in the primary intervention because few of their previous WL attempts involved a registered dietitian or even a credible source of dietary information. Registered dietitians are a credible source of reliable and truthful nutrition education information regarding weight management (Seagle et al., 2009) and possess the skills and knowledge to encourage individuals throughout their weight management efforts. Including registered dietitians in future programmes may provide additional means of support, as well as access to accurate nutrition information.

Portion distortion was an overwhelmingly common phenomenon in the present study sample, as well as in other segments of the US population. Once women recognised their own 'portion distortion', implementing reduced portion sizes and portion control of foods promoted weight loss (Ello-Martin et al., 2005; Seagle et al., 2009; Sciamanna et al., 2011). Additionally, individuals who consume smaller portion sizes are generally more successful in maintaining WL

and achieving WLM (Wing & Hill, 2001; Elfhag & Rossner, 2005; Sciamanna et al., 2011). These results are consistent with those of Jeffery et al. (1993), who documented that consuming portion-controlled servings aided in WLM and with those of Hannum et al. (2004) who observed significant WL in individuals consuming portion-controlled entrees. Furthermore, individuals in a previous qualitative study reported portion control as a common strategy for WLM (Reyes et al., 2012). Along with consuming appropriate portions, regularly consuming breakfast and making healthy snack choices were noted as positive changes in the eating patterns of women in the present study. These findings are consistent with others (Elfhag & Rossner, 2005; Wing & Phelan, 2005; Seagle et al., 2009). Although a standard definition for snack (Gregori & Maffei, 2007; Gregori et al., 2011) has not been agreed upon, being able to distinguish between snacks and snack foods proved to be beneficial in controlling weight and satisfying nutrient and food group requirements. A recent cross-sectional analysis found snacking to be positively associated with overall diet quality and a more nutrient-dense diet (Zizza & Xu, 2012). Along with portion control strategies, flexible approaches to eating should be encouraged in future interventions and dietary programmes.

Regular participation in exercise has been associated with long-term WLM and has been identified as a common strategy of National Weight Control Registry participants for WL and WLM (Kayman et al., 1990; Wing & Hill, 2001; Elfhag & Rossner, 2005; Sciamanna et al., 2011). The primary intervention did not include an exercise component; however, following the intervention, women recognised the importance of physical activity in maintaining WL. Women who reported the most success at WLM adopted some form of exercise, whereas women who were not successful recognised that a lack of exercise may have played a role in weight regain. Barriers to exercise, including guilt, a lack of time and unenjoyable activities, are consistent with those reported by Thomas et al. (2008) and represent factors that should be considered in future interventions.

Weight loss is generally a function of time, whereas WLM is the result of sustained actions over time (Reyes et al., 2012). Women recognised that 'quick fixes' and fad diets were not sustainable and did not produce long-term results; rather, women recognised that lifestyle changes were necessary to achieve long-term WLM. This finding is consistent with the study of

Herriot et al. (2008), who reported that shifting from a dieting attitude to a permanent lifestyle change was predictive of successful WL. Lifestyle modifications that include sustainable diet, exercise and behaviour therapy components have been shown to produce significant WL and aid in long-term weight control (Lyznicki et al., 2001; Wadden et al., 2004) and should be included in future trials.

A novel finding of the present study is that women never reported that self-accountability was important to them or that self-monitoring of body weight was central to WLM. This finding is in contrast to practices of National Weight Control Registry members, who use self-weighing as a form of self-monitoring and self-accountability as a means for motivation to achieve long-term WLM (Wing et al., 2006). In the present study, all women used the same approach to induce WL and self-monitoring was not emphasised. Inclusion in the National Weight Control Registry and the study by Wing et al. (2006) was based on WL and WLM standards, regardless of the approach used to achieve WL and WLM. Some of these interventions may have encouraged self-weighing and monitoring and self-accountability. Group-based interventions, such as in the present study, appear to provide an important source of support for healthy eating and physical activity behaviours (Wang et al., 2014); thus, social support from study participants and accountability to external others may have been more important than self-accountability or self-monitoring of body weight. Only a few women in the present study reported using clothing fit as a means of self-monitoring of body weight, a practice commonly reported in other studies (Klem et al., 1997; Wing & Phelan, 2005; Hindle & Carpenter, 2011; Reyes et al., 2012). Different self-regulation and self-monitoring techniques may be necessary to assist individuals in their WL and WLM efforts.

The limitations of the present study include the use of a convenience sample and limited generalisability to other populations. Although these results may not be generalisable to other populations, they do provide understanding and insight into experiences and perceptions of participants. Large focus groups were not conducted as a result of the restricted number of participants; however, the topic of interest was still explored in-depth among this small homogenous sample of women who participated in the same WL intervention. Although successful at achieving WL during the primary intervention, most participants were not

successful at WLM. Additional research is warranted to further explore psychosocial and behavioural characteristics of optimal WL and WLM strategies through programmes and interventions that will assist women with their weight management journeys.

In conclusion, the qualitative findings of the present study indicate that perceived accountability to others, social support, planning ahead, awareness and mindfulness of food choices, basic nutrition education, portion control, exercise and self-motivation all facilitated WL and WLM. Barriers included life transitions, health status changes, internal factors, environmental pressures, lack of accountability to others and an absence of social support. Because women considered WLM to be more difficult than WL, as demonstrated by the fact that the overall sample was not successful at WLM, the different strategies necessary to achieve WL and WLM should be acknowledged. Therefore, future interventions should incorporate WLM strategies for the prevention of undesired weight gain or weight regain following WL. The identification of facilitators and barriers to WL and WLM provides direction for future interventions and programmes that promote robust and sustainable behaviour changes for women during their weight management journeys.

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CJM and SNR designed the study, collected data and drafted the paper. All authors analysed and/or interpreted data, and also critically reviewed the manuscript and approved the final version submitted for publication.

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**Table 3.4** Focus group questions used during a qualitative study exploring weight loss and weight-loss maintenance in 23 women from a primary weight-loss study

Question	Theoretical model	Behavior change variable
1. Very briefly, would anyone like to share about their weight loss journey?*		
2. How was your experience with weight loss in this study different from previous experiences of managing your weight?*	Theory of planned behavior	Attitudes
3. If you learned any strategies during this weight loss experience that have helped you maintain weight loss, please describe these strategies.	Theory of planned behavior Social cognitive theory	Skills Self-efficacy
4. Explain your success in maintaining weight loss or experiencing further weight loss.	Theory of planned behavior Social cognitive theory	Skills Self-efficacy
5. Explain any difficulties in terms of maintaining your weight loss or achieving further weight loss.*	Health belief model	Barriers
6. How do you think a close friend would describe you/your experience with weight management/weight loss/weight regain?*	Theory of planned behavior	Subjective norms
7. If you were writing a self-help book about managing your weight, or advising a friend, what would be the key points you would want to make?*	Theory of planned behavior	Skills; Subjective norms
8. How has your change in lifestyle and/or weight affected those close to you?*	Theory of planned behavior	Subjective norms
9. Have your eating patterns changed since participation in the study?	Theory of planned behavior Social cognitive theory Health belief model	Attitudes Outcome expectations Barriers
10. How do you feel about snacks since your experience with weight loss?	Social cognitive theory	Outcome expectations

\*Hindle & Carpenter (2011)

**Table 3.5** Descriptive statistics of women participating in focus group discussions compared to nonparticipants

Characteristic	Focus group participants: current <sup>†</sup>	Focus group participants: post-intervention <sup>‡</sup>	Nonparticipants <sup>§</sup>
Age (years)	38.8 (6.0)	35.7 (5.8)	39.0 (5.6)
Height (cm)	164.6 (4.9)	164.6 (4.9)	165.0 (6.6)
Weight (kg)	80.7 (17.4)	77.9 (16.7)	79.0 (12.4)
Body mass index (kg/m <sup>2</sup> )	30.0 (6.2)	28.7 (5.5)*	29.0 (4.1)
Waist circumference (cm)	88.4 (15.0)	83.0 (12.0)***	85.7 (9.5)
Hip circumference (cm)	113.3 (11.5)	110.1 (11.9)*	110.0 (9.5)

Data are reported as the mean ± SD.

\*P < 0.05; \*\*P < 0.01; \*\*\*P < 0.001 for comparison of current to week 18 measurements within focus group participants, using paired t-tests.

<sup>†</sup>Data collected during the day of focus group session; participants (n = 23) included those engaging in focus group discussions.

<sup>‡</sup>Data collected at week 18 of the primary intervention study (post-intervention); participants (n = 23) included those engaging in focus group discussions.

<sup>§</sup>Data collected at week 18 of the primary intervention study (post-intervention); nonparticipants (n = 28) included those who declined to participate (n = 12) and those lost to follow-up after the primary study (n = 16).



**Table 3.6** Summary of major themes (mentioned by at least three participants across groups), interpretation of meanings and considerations for future interventions regarding facilitators and barriers to weight loss and weight loss maintenance as perceived by a group of 23 women who participated in focus group sessions after completing a primary weight loss study

Themes	Interpretations	Considerations for future interventions
Weight loss journey	<p>Women perceive their weight loss journeys to be continuous processes that include the use of various approaches to induce weight loss or to manage weight.</p> <p>Biological and physiological challenges to weight loss and weight loss maintenance exist for women.</p> <p>Women desire to prevent weight gain across life transitions.</p>	<p>Tailor programs to individual needs, given a woman’s biology, physiology and life stage.</p>
Accountability and support	<p>External accountability is preferred during weight loss and weight loss maintenance.</p> <p>A high level of support is needed from many social sectors during weight loss maintenance.</p>	<p>Incorporate external accountability strategies and protocols into interventions.</p> <p>Provide and/or build social support networks in programs for weight loss and weight loss maintenance.</p>
Planning ahead, mindfulness and awareness	<p>Planning is an important aspect for achieving successful weight loss and weight loss maintenance.</p> <p>Planning skills take time to develop and maintain.</p> <p>Planning is inherently linked to mindfulness and awareness of food choices and energy intake.</p>	<p>Incorporate planning skills into interventions that are practical, simple and provide structure.</p> <p>Practice and reinforce planning skills during programs to enhance mindfulness of food intake and awareness of energy and nutritional content of foods as part of daily caloric intake.</p>

**Table 3.6 (cont.)**

Nutrition education	<p>Group nutrition education sessions and discussions provide valuable knowledge, necessary to making healthier food choices.</p> <p>Credibility of the registered dietitian as an expert is valued; access to a credible source of information post-intervention is desired.</p>	<p>Include routine education classes, led by a registered dietitian, for dissemination of accurate nutrition information.</p> <p>Offer registered dietitian services during weight loss and weight loss maintenance interventions.</p>
Portion control	Regulation of portion sizes and recognition and avoidance of portion distortion is a major facilitator of weight loss and weight loss maintenance.	Incorporate portion control strategies and education into interventions.
Exercise	<p>Regular exercise facilitates weight loss maintenance.</p> <p>Lack of exercise is a key barrier to success with weight loss maintenance.</p>	Incorporate preferred and tailored exercise routines into interventions; provide appropriate technical supervision as needed.
Motivation	<p>Preventing minor dietary indiscretions from turning into large relapses of weight gain is critical for weight loss and weight loss maintenance.</p> <p>Self-motivation plays a key role in weight loss maintenance.</p> <p>Identification of readiness for change is helpful to predict weight loss and weight loss maintenance success.</p>	<p>Create and discuss scenarios that test self-control, willpower and self-regulation for relapse prevention. Discuss self-forgiveness for noncompliance.</p> <p>Include skills and strategies for maintaining motivation and sustaining change.</p>
Total lifestyle change	Avoiding a “dieting” or “quick fix” mentality and shifting toward a total lifestyle approach for weight loss and weight loss maintenance is crucial to success.	Include strategies for sustainable dietary and physical activity modifications in interventions.

**Table 3.6 (cont.)**

Eating patterns and snacking	Women perceive healthy snacks to be a necessary component of dietary approaches for weight management.  A consistent eating pattern is found to be valuable in weight loss and weight loss maintenance.	Encourage flexible and accommodating approaches to eating, including regular consumption of breakfast, healthy snacks and a consistent eating pattern.
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## CHAPTER 4: Materials and methods

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Chapter 4 describes the materials and methods for the current dissertation research which focuses on weight gain prevention in young adult and midlife women. The current research emphasizes prevention of weight gain, rather than treatment of excess body mass by weight loss, as few individuals are successfully able to lose and maintain weight loss over the long term.

These materials and methods are grounded in findings from preliminary research as well as methodology from previous studies examining weight gain prevention in adult populations (1). The current study is unique in that it focuses only on women, but includes normal weight, overweight and obese women. Previous weight gain prevention studies that have included women have studied normal weight and overweight women *or* overweight and obese women.

This study is also unique in that it employs interactive nutrition education classes as the intervention to provide basic nutrition education and knowledge to assist participants in preventing weight gain over the course of one year. Additionally, this study compares the education classes delivered by a trained nutrition professional (i.e. a registered dietitian) with individuals matched for gender and age with no formal nutrition training.

Expected results of the study are presented in this chapter; major findings and results from this research are presented in Chapters 5, 6 and 7.

## Reference

1. This chapter previously appeared in its entirety as Metzgar CJ, Nickols-Richardson SM. Determinants of weight gain prevention in young adult and midlife women: study design and protocol of a randomized controlled trial. *JMIR Res Protoc.* 2015;4(1):e36. doi:10.2196/resprot.4008. This is an open-access article (<http://www.researchprotocols.org/2015/1/e36/>) distributed under the terms of the Creative Commons Attribution License and the authors retain copyright.

## Determinants of weight gain prevention in young adult and midlife women: study design and protocol of a randomized controlled trial<sup>3</sup>

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### **Abstract**

**Background:** Treatment of overweight and obesity through body weight reduction has been monumentally ineffective as few individuals are able to sustain weight loss. Rather than treating weight gain once it has become problematic, prevention of weight gain over time may be more effective.

**Objective:** The aim of this research is to preclude the burden of adult obesity in women by identifying the determinants of weight gain prevention. The objective of this randomized controlled trial (RCT) is to compare a weight gain prevention intervention delivered by the registered dietitian versus counselor.

**Methods:** This is a 12-month parallel-arm weight gain prevention RCT designed to increase self-efficacy, self-regulation, outcome expectations and family and social support through the use of a nutrition education intervention in women, aged 18-45 years, from the Urbana-Champaign (Illinois, USA) area. Women have been randomized to registered dietitian, counselor or wait-list control groups (August 2014) and are undergoing weekly nutrition education sessions for four months, followed by monthly sessions for eight months (through August 2015). Outcome measures, including: (1) dietary intake, (2) physical activity, (3) anthropometric and blood pressure measurements, (4) biochemical markers of health, (5) eating behaviors and health perceptions, and (6) mediators of behavior change, were collected before the intervention began (baseline) and will be collected at 3, 6, 9, and 12 months of the study.

**Results:** In total, 87 women have been randomized to intervention groups, and 81 women have completed first week of the study. Results are expected in early 2016.

**Conclusions:** This RCT is one of the first to examine weight gain prevention in women across normal, overweight, and obese body mass index categories. Results of this research are

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<sup>3</sup>This chapter previously appeared in its entirety as Metzgar CJ, Nickols-Richardson SM. Determinants of weight gain prevention in young adult and midlife women: study design and protocol of a randomized controlled trial. *JMIR Res Protoc*. 2015;4(1):e36. doi:10.2196/resprot.4008. This is an open-access article (<http://www.researchprotocols.org/2015/1/e36/>) distributed under the terms of the Creative Commons Attribution License and the authors retain copyright.

expected to have application to evidence-based practice in weight gain prevention for women and possibly have implication for policy regarding decreasing the encumbrance of overweight and obesity in the United States.

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**KEYWORDS**

body weight; weight gain prevention; weight maintenance; women

## *Introduction*

### **Adult Weight Management**

Small weight gains over time, around 1-2 pounds per year [1,2], contribute to the development of overweight and obesity. Once established, obesity is difficult to treat [3], as reduction of excess body weight is rarely effective in the long term. Short-term weight loss can be achieved by a variety of methods, but few of these approaches are sustainable and effective in facilitating permanent weight loss [4-10]. On average, individuals adhere to weight loss programs for approximately six months [11]; following weight loss, most individuals regain half of the weight lost within one year, and return to baseline weight within 3-5 years [11-13]. Weight gain prevention, on the other hand, avoids the difficulties that may accompany weight loss and its maintenance and offers an alternative option for weight management.

To reduce disease risk and improve overall health, effective weight gain prevention is essential; however, few interventions have successfully examined weight gain prevention and little is known about the determinants of and strategies for preventing weight gain over the long term. Much of the existing research has focused on treatment of overweight and obesity through reduction of excess body weight [14,15] or prevention of weight regain following weight loss [16-20].

### **Weight Gain Prevention**

In the first weight gain prevention trial, normal weight adults, aged 25-74 years, were randomized to an untreated control group or a treatment group that received monthly newsletters plus a financial incentive for weight maintenance for one year [21]. The treatment group experienced an average weight loss of 1 kg, which was significantly different from the control group; with the treatment effect being stronger in men than women [21]. Building upon the Pound of Prevention (POP) work, 3-year weight gain prevention in adults, aged 20-45 years, was investigated [22,23]. Participants were randomized to a no-contact control group or to one of two education groups that received nutrition education via monthly newsletters and semiannual nutrition and exercise classes. One education group received a lottery incentive for



participation. Significant differences in weight gain between the control and education groups were not found, although weight-related behaviors did improve in participants receiving education [22,23].

The Shape Program was a medium-intensity behavioral intervention in overweight and class I obese premenopausal black women that included weekly self-monitoring, monthly counseling calls, tailored skills training and a YMCA gym membership and was compared to usual care that included newsletters covering general wellness topics every six months during the 18-month study [24]. After one year, weight loss was significantly greater in the intervention group; these changes were sustained at 18 months. No significant differences in waist circumference, blood pressure, glucose or lipid levels between the intervention and usual care groups were observed at any measurement point during the study [24]. Levine and colleagues [25] randomized normal weight and overweight women to a clinic-based group, a correspondence group or a control group for 24 months. During three years, the intervention had no influence on weight gain in either group; however, age, dieting status, and feelings of hunger were found to be predictive of weight gain.

The Groningen Overweight and Lifestyle (GOAL) study examined weight gain prevention in overweight and obese men and women with hypertension and/or dyslipidemia in the Netherlands by comparing the effects of lifestyle counseling by a nurse practitioner to usual care from a general practitioner during a 1-year period [26]. No significant differences were observed in weight change between groups at one year or after three years [26,27]. Study of Novel Approaches to Weight Gain Prevention (SNAP) is the most recently published intervention [28]. Two novel self-regulation approaches to weight gain prevention—small consistent changes and large periodic changes—were compared to a minimal treatment control for an average of three years of follow-up. Results of this study have not yet been published [28]. Without complete knowledge of the determinants of and strategies for weight gain prevention, public health will remain at risk for complications and costs related to overweight

and obesity. Weight gain prevention offers a primary strategy for weight management and obesity prevention [24,26].

Women who previously participated in a weight-loss intervention identified gender-specific life transitions and stressors, including pregnancy, post pregnancy, family responsibilities, health status changes, and aging as precipitators of weight gain [29]. Young adulthood and perimenopause appear to be critical intervals for weight gain [30-32]; therefore, weight gain prevention efforts should target these lifespan stages, specifically in women.

### **Aims and Objectives**

The current study aims to identify determinants of weight gain prevention in young adult and midlife premenopausal women through a 1-year weight gain prevention intervention that includes nutrition education. We hypothesize that compared to a wait-list control group, women who participate in a weight gain prevention intervention designed to increase self-efficacy, self-regulation, outcome expectations, and family and social support will maintain current body weight during a 12-month period. It is further hypothesized that women in an intervention group led by registered dietitians will have less weight gain during 12 months compared to women in an intervention group led by counselors.

### *Methods*

#### **Recruitment, Screening, and Enrollment**

Participants were recruited by word-of-mouth, electronic mail messages, and posted flyers from the University of Illinois campus and the Urbana-Champaign (IL, USA) communities. A flow diagram of response, screening, and randomization steps is displayed in Figure 4.1. A total of 330 women responded to recruitment methods, between June and August 2014. Of these, 266 women met prescreening criteria (appropriate age, body mass index [BMI], and desire to prevent weight gain) and received screening materials including a medical history form, Zung Self-Rating Depression Scale/Status Inventory [33], and informed consent. A total of 146 women returned screening materials, which were reviewed by investigators. One hundred two

women met eligibility criteria for participation, and 87 women were randomized, with 81 women completing baseline testing.

The current study included premenopausal women between the ages of 18-45 years with a BMI of  $>18.5$  kg/m<sup>2</sup>. There were no additional criteria for body weight and BMI to ensure participation by women from a range of weight status categories. Further inclusion criteria included eumenorrhea ( $\geq 8$  menstrual cycles/year), score of  $<50$  on the Zung Self-Rating Depression Scale/Status Inventory [33], and no self-reported metabolic, cardiovascular or musculoskeletal diseases or use of medications or supplements to manage a chronic health condition. Exclusion criteria included women who currently smoked, were pregnant or attempting to become pregnant or were currently lactating. Women using medications influencing weight regulation, such as steroid or thyroid hormones or oral contraceptives, were excluded if use was for  $<2$  months before the start of the study. Gastric bypass surgery was also an exclusion criterion.

The Institutional Review Board (IRB) for the protection of human subjects at the University of Illinois at Urbana-Champaign (UIUC) approved the study protocol (UIUC IRB#14397). Each participant provided written informed consent before study participation.

### **Study Design**

The current study is a 12-month parallel-arm weight gain prevention randomized controlled trial. After enrollment, women were randomized to one of three intervention groups: (1) weight gain prevention intervention delivered by a registered dietitian (RDG); (2) weight gain prevention intervention delivered by a counselor (CSG), or (3) wait-list control (CON) group. The RDG and CSG weight gain prevention interventions are identical in materials and content; the only difference is the credentialing of the individuals leading the intervention. Women in the CON group receive no intervention; upon completion of the 12-month waiting period, these women will be randomized to the RDG group or CSG group and will receive the respective intervention for the next 12-month period.

## **Intervention**

During the 1-year study, women randomized to the RDG and CSG groups will attend a total of 24, 1-hour nutrition education sessions that are based on effective weight-loss programs/plans which address energy balance through sustainable diet, exercise, and behavior modifications [30,34-39]. These sessions will be held weekly for 16 weeks (months 1-4) and monthly thereafter (months 5-12) [30]. Vegetable consumption, planning ahead for food intake and portion control will be emphasized [34,35], and general nutrition information, eating away from home, food selection, food preparation, and recipe modification also will be addressed [34-37]. Other topics will include fitness and physical activity, culinary skills, breakfast consumption, healthy snacking and beverage choices, nutrient density, family menu planning, and grocery shopping. Problem solving, motivational concerns, and stress management will be encouraged [30,34-39]. Education sessions will relay constructs of the Social Cognitive Theory (SCT) [40].

Education sessions will follow a three-part format. Each session will begin with a brief review of information covered in the previous session and will address participant progress, including successes, challenges and questions. Next, the leader will deliver the nutrition education component of the session using an interactive group discussion format. Participants will be provided with handouts addressing food choices, dietary patterns, menu plans, and other information pertaining to the lesson. Finally, the content for the lesson will be summarized and participants will have a chance to ask questions, address concerns and set specific behavioral goals for the next session. Education sessions will be randomly selected for evaluation by a process observer who will rate the sessions based on investigator-established criteria.

Four registered dietitians will deliver the intervention to women in the RDG group. All women in the RDG group will equally interact with all four registered dietitians during the study. Four counselors will deliver the intervention to women in the CSG group, with these women having equal interaction with all four counselors across the study. The credentials of the professionals delivering the intervention will not be revealed to participants until after completion of the study. The registered dietitians are all female and have been practicing for <5 years. The

counselors are all female and are graduate teaching assistants at UIUC in programs unrelated to nutrition or dietetics. Compliance will be defined as attendance of >85% of education sessions. If women are unable to attend an education session, virtual make-up sessions will be offered, along with a quiz. Completion and return of the quiz will indicate that the materials were studied and reviewed and that the participant was compliant.

### **Outcome Measures**

Before the intervention (baseline), data on dietary intake, physical activity, anthropometric, and blood pressure measurements, biochemical markers of health, eating behaviors and health perceptions, and SCT mediators of behavioral change were collected. These outcome measures also will be obtained at 3, 6, 9 and 12 months.

### **Dietary Intake and Physical Activity Assessment**

Participants were taught to accurately complete 4-day food records and the Stanford 7-Day Physical Activity Recall Scale [41]. To ensure accuracy in recording foods and beverage consumption, handouts containing examples of standard serving sizes were provided. Participants recorded all food and beverages consumed for three non-consecutive weekdays and one weekend day before the baseline testing session [35]. Four-day food records will be analyzed using the Nutrition Data System for Research (NDSR) dietary analysis software (Nutrition Coordinating Center, Minneapolis, MN, USA) to estimate average daily dietary intake of total energy (kcal/day), carbohydrate (g/day), protein (g/day), fat (g/day), and fiber (g/day) in addition to intake by food groups (svgs/day).

For seven consecutive days before the baseline testing session, participants recorded the number of hours slept, spent in front of a television or computer screen, and engaged in moderate, hard, and very hard physical activity [35]. Participants wore accelerometers at the waist, wrist, or ankle during all waking hours for seven consecutive days while also recording physical activity to provide an objective assessment of energy expenditure. Approximately 70% of participants in each group wore accelerometers as they were not available for all individuals.

Physical activity records will be analyzed by summing total hours of moderate, hard, and very hard activity and dividing by seven to estimate hours of physical activity per day. These records will be further analyzed by converting activities into metabolic equivalents (METs) (hr/d), which will be evaluated as light activity (1-3 METs), moderate activity (>3-6 METs), and vigorous activity (>6 METs) to estimate the number of calories expended per day. Accelerometry data will be analyzed using ActiLife 6.11 (ActiGraph, Pensacola, FL, USA) to estimate the number of calories expended per day, the MET rate per day, and the length of time (minutes) spent in sedentary, light, moderate, vigorous, and very vigorous activities.

### **Anthropometric and Blood Pressure Measurements**

Baseline standing height (cm) was recorded to the nearest 0.1 cm using a calibrated scale-mounted stadiometer (Seca 700, Hanover, MD, USA). Body weight (kg) was measured using a calibrated scale (Tanita 410GS, Arlington Heights, IL, USA) to the nearest 0.1 kg. BMI ( $\text{kg}/\text{m}^2$ ) was calculated using height and body weight measurements. A retractable measuring tape (Gulik II, Country Technology, Inc, Gay Mills, WI) was used to measure waist (cm) and hip (cm) circumferences, in duplicate, to the nearest 0.1 cm according to standard protocol [34]. Waist circumference was measured at the narrowest point of the waist, approximately one inch above the navel, and hip circumference was measured at the widest part of the buttocks [35]. Waist and hip circumference measurements were averaged to obtain a single value for each site; these values were used to calculate the waist:hip ratio. Fat mass (FM; kg) and body fat percentage (BF%) were measured using a Tanita scale (410GS).

Seated systolic and diastolic blood pressures (mm Hg) were measured by a trained study investigator using a standard sphygmomanometer (Baumanometer® Desk Model, Copiague, NY, USA) following a 5-minute rest period. Blood pressure measurements were taken in duplicate with a 2-3-minute rest period between readings; mean systolic arterial pressure values and diastolic arterial pressure values will be used in data analyses. Resting heart rate was also measured after the 5-minute rest period.

### **Biochemical Markers of Health**

Venous blood samples (~30 mL) were collected by a trained phlebotomist between 7:00 to 9:30 AM after a 12-hour fast. Whole blood samples were processed and stored at -80°C. Serum will be analyzed for concentrations of insulin, glucose, total cholesterol, high-density lipoprotein-cholesterol (HDL-C), low-density lipoprotein-cholesterol (LDL-C), triacylglycerides (TG), leptin, adiponectin, and resistin.

Serum insulin ( $\mu\text{U/mL}$ ) (LINCO Research, St Charles, MO, USA) will be measured using enzyme-linked immunosorbent assay (ELISA), and serum glucose (mg/dL) (Stanbio Labs, Boerne, TX, USA) will be measured by spectrophotometry. Total cholesterol (mg/dL), HDL-C (mg/dL) and TG (mg/dL) concentrations will be measured by spectrophotometry using the total cholesterol, HDL-C and TG kits, respectively (Stanbio Labs). Total cholesterol, HDL-C and TG concentrations will be used to calculate LDL-C concentration (mg/dL) using the equation:  $\text{LDL-C} = \text{total cholesterol} - \text{HDL-C} - (\text{TG}/5)$  [42]. Serum leptin (ng/mL), adiponectin (ng/mL), and resistin (ng/mL) will be measured using ELISA (R&D Systems, Minneapolis, MN, USA). All serum samples for each biomarker will be analyzed in duplicate at corresponding study intervals. Intra- and inter-assay coefficients of variations (CV) are <15% for all kits.

### **Eating Behaviors, Health Perceptions, and SCT Mediators of Behavioral Change**

Participants completed questionnaires designed to evaluate eating behaviors, health perceptions, perseverance, and SCT mediators. The Eating Inventory [43] will evaluate ratings of cognitive eating restraint, hunger, and disinhibition. The Short-Form 36 Health Survey (SF-36) [44] will assess self-reported health issues. Perseverance will be examined using the Short Grit Scale (Grit-S) [45], and an investigator-designed questionnaire will evaluate SCT mediators, including self-efficacy, outcome expectations, self-regulation, and social and family support. Standard scoring and interpretation methods will be used to evaluate all questionnaires [43-45].

## **Statistical Analysis**

Baseline characteristics of study participants were characterized using descriptive statistics: mean (SD). Participants in the three intervention groups (Treatment) will participate in five data collection sessions at specified intervals (Time). The Shapiro-Wilk test for normality will be used to test for normality and homogeneity of variance within groups; data will be transformed if necessary. Body weight, BMI, waist : hip ratio, FM, BF%, systolic and diastolic blood pressure, serum insulin, glucose, TC, HDL-C, LDL-C, TG, leptin, adiponectin, and resistin will be analyzed as dependent variables. Baseline variables that differ between groups will be included as covariates in the analysis. Dietary intake of macronutrients as estimated from 4-day food records, estimated energy expenditures, eating behaviors, health perceptions, and ratings of SCT mediators also will be compared among groups. A 3 x 5 (3 treatment groups x 5 time intervals) ANOVA with repeated measures on the time factor will be used to assess differences in outcomes within and between treatment groups over time. The group by time interaction will be examined for differences in time trend among intervention groups. Tukey pairwise comparisons will be used in conjunction with ANOVA to detect differences between treatment groups.

Some attrition is expected, as participants may be unable to comply with the intervention or may choose not to continue participation in the study. Participants who withdraw from the intervention will be asked to complete any remaining data collection sessions, and these data will be included in the statistical analyses (ie, intention-to-treat model). Data also will be analyzed using measurements only from those participants who complete all testing sessions. Statistical tests will be two-tailed with significance set at  $P < .01$  to reduce the potential for Type I error. All statistical analyses will be conducted using Statistical Package for the Social Sciences (version 22.0, 2013, IBM Corp, Armonk, NY, USA).

## *Results*

Eighty-one women completed baseline testing. Baseline descriptive characteristics of the sample are displayed in Tables 4.1 and 4.2. Overall, these women were highly educated, with a



majority of participants having at least a 4-year college degree. The racial/ethnic breakdown was reflective of the larger population, with non-Hispanic whites representing the majority. Age range was 18-45 years, and BMI range was 18.5-49.6 kg/m<sup>2</sup>. On average, participants were overweight and normotensive. Participants have been recruited, enrolled, and randomized to one of the three intervention groups. Education sessions will continue through August 2015, and results are expected by early 2016.

## *Discussion*

### **Principal Findings**

The importance of weight gain prevention and maintenance of current weight has recently been recognized by the American College of Sports Medicine [18] and Healthy People 2020 [46] as critical; yet, there are currently no treatment guidelines for weight gain prevention. The gap in the understanding of the determinants, facilitators, and barriers to weight gain prevention likely exists due to the limited number of studies addressing prospective weight changes in adulthood. Awareness and identification of the determinants of weight gain prevention are necessary in order to increase the practicality of weight gain prevention for managing obesity. While it may seem counterintuitive to promote weight gain prevention in overweight and obese individuals rather than weight loss, weight gain prevention is relevant for individuals of all BMI categories [47]. Preventing weight gain over time offers the opportunity to slow the progression of overweight and obesity and to avoid further exacerbations related to excess body weight in individuals who are already overweight or obese [48]. Additionally, weight gain prevention may require less intensive treatment than that required to achieve weight loss [2], and may be more successful in the long term as it avoids the problems associated with weight loss and its maintenance [27]. Weight maintenance, regardless of whether an individual is normal weight, overweight or obese, may be more beneficial and practical than repeated, minimally successful weight-loss attempts. While modest weight losses of 5-10% of body weight have significant effects on risk factors of disease, these benefits may be ameliorated with weight regain. Even with weight loss, metabolically healthy obese individuals may not show improvement in health outcomes, and weight loss in these individuals may promote

weight cycling, or periods of weight loss followed by weight gain, which may have detrimental effects on mental, metabolic, and psychological outcomes [48-52]. Further, the adverse effects associated with weight cycling may be as harmful as maintenance of a high “unhealthy” body weight [51]. However, a recent study by Mason and colleagues [53] found that weight cycling was not associated with negative metabolic outcomes and a history of weight cycling was not related to the ability to lose and successfully maintain weight in the long term.

In a recent qualitative study of women who completed a weight-loss intervention conducted by a registered dietitian, women perceived the registered dietitian to be a credible source of nutrition information and found lack of access to a registered dietitian following completion of the intervention to be a barrier to weight-loss maintenance [29]. As a credible source of nutrition information [37], registered dietitians have a specialized skill set to support and encourage sustainable behavior changes to achieve weight management. Registered dietitians are generally regarded as the experts in weight management, but no studies have compared registered dietitians to other health professionals in the delivery of weight management information. The current study will fill this scientific gap by testing the ability of the registered dietitian to promote weight gain prevention as compared to an untrained professional. If registered dietitians are more effective in promoting weight gain prevention, these findings will support the notion that registered dietitians should be at the forefront in helping individuals attain successful weight management.

Women in the qualitative study [29] identified social support, basic nutrition education, accountability to others, self-motivation, mindfulness and awareness of food choices, planning ahead, portion control, and exercise as facilitators to weight loss and weight-loss maintenance while health status changes, environmental pressures, life transitions, absence of social support, lack of accountability, and internal factors were perceived as barriers. Additionally, women expressed their desire for continual contact with the registered dietitian as well as the group support offered by the education sessions [29].

Although there is no standardized definition of weight gain prevention or weight maintenance, a weight change of  $\pm 3\%$  from baseline weight will be considered successful weight gain prevention. A 3% change criterion allows for normal day-to-day fluctuations that may result from measurement error, clothing, food consumption, and/or fluid balance [54].

### **Limitations**

Results from this study will be limited in generalizability to premenopausal women. Future research should examine pre- and post-menopausal women, as these physiological changes appear to be other critical life stage intervals for weight gain. Weight gain prevention should also be examined exclusively in men, as determinants of and strategies for weight gain prevention may differ between men and women. Further, our results may be limited by the length of the study, as the current intervention is only for one year. Surveys, testing sessions or focus groups following completion of the intervention may be useful in order to garner more information about the feasibility of long-term weight gain prevention. There are limitations with using self-reported dietary intake and physical activity; however, participants have been taught to accurately complete food records, and accelerometry data will be used to validate written physical activity records. Finally, our intervention contains multiple components that address weight gain prevention, and the study design does not allow for examination of independent effects of the different elements of this weight gain prevention intervention. Investigator-designed surveys will be used to assist with determining the effects of individual intervention components.

### **Conclusions**

The current study targets women who are at greater risk for weight gain compared to men; with the goal to help further the understanding of the determinants of weight gain prevention [29]. This study will fill a scientific gap in testing the ability of a registered dietitian to promote weight gain prevention as compared to another health professional that lacks formal nutrition and dietetics training. Although several studies have explored weight gain prevention with limited success, this may be the first study that targets young adult and midlife women of all

weight status categories (normal weight, overweight, obese) and focuses on prospective weight gain prevention. Results of this research will be expected to have implications for policy development and recommendations for decreasing the burden of overweight and obesity in the United States through weight gain prevention.

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### **Authors' Contributions**

CJM and SMN-R contributed equally to the conceptual development, research design, and drafting of the manuscript. CJM was the lead investigator for data collection and analysis, to date. Both authors contributed equally to data interpretation and critical revision of the manuscript.

### **Conflicts of Interest**

CJM discloses Graduate Research Fellowship funding from The Hershey Company. SMN-R discloses research funding from The Hershey Company; the Bell Institute of Health and Nutrition, General Mills, Inc; Dairy Research Institute; and the United States Department of Agriculture. Research funding provided to SMN-R is unrelated to the present study.

### **Multimedia Appendix 1**

CONSORT-EHEALTH checklist V1.6.2 [55].

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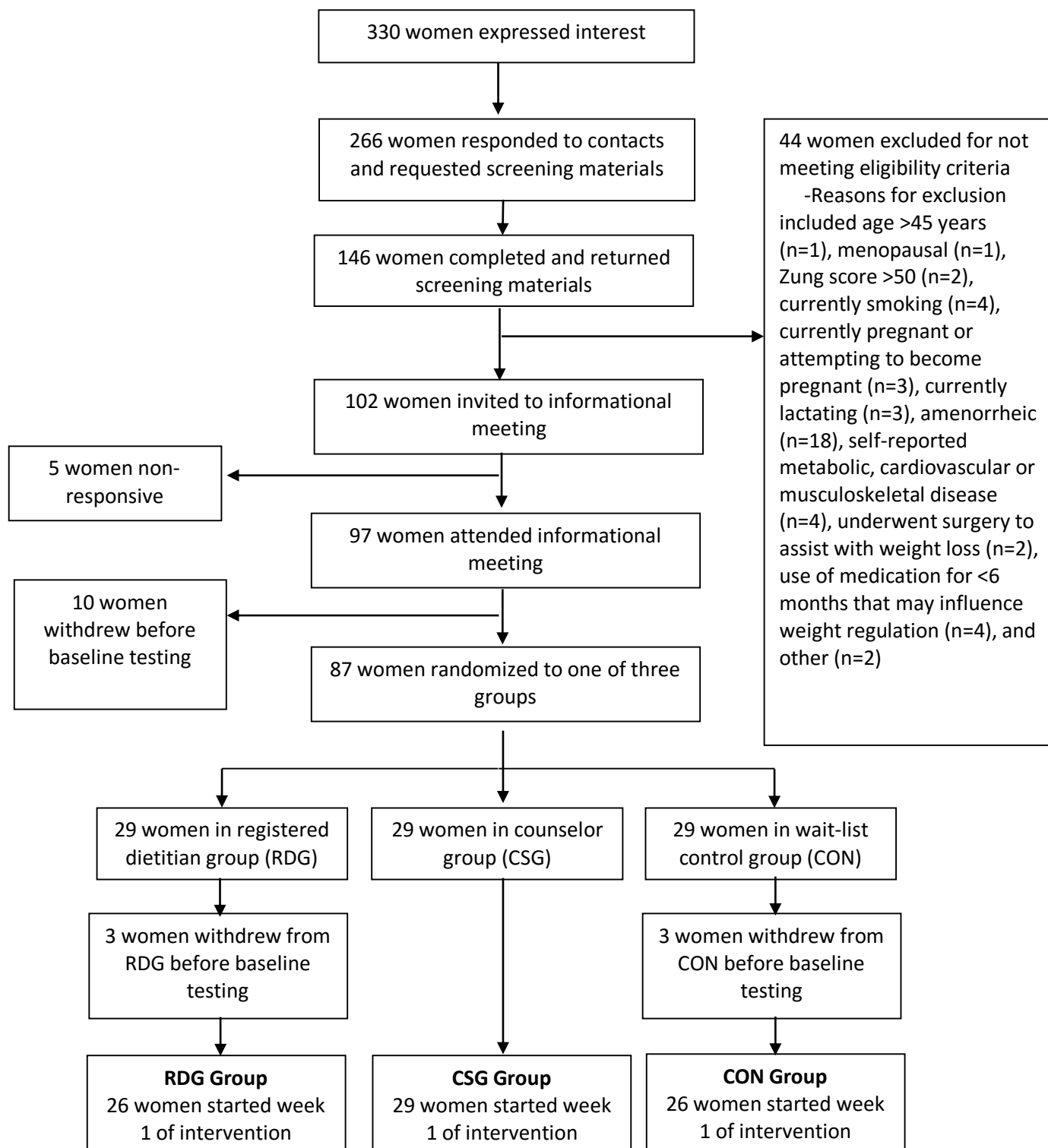
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## Abbreviations

**BF%:** body fat percentage  
**BMI:** body mass index  
**CON:** control group  
**CSG:** counselor group  
**CV:** coefficients of variations  
**FM:** fat mass  
**GOAL:** Groningen Overweight and Lifestyle  
**Grit-S:** Short Grit Scale  
**HDL-C:** high-density lipoprotein cholesterol  
**IRB:** Institutional Review Board  
**LDL-C:** low-density lipoprotein cholesterol  
**MET:** metabolic equivalent  
**NDSR:** Nutrition Data System for Research  
**POP:** Pound of Prevention  
**RDG:** registered dietitian group  
**SCT:** social cognitive theory  
**SF-36:** Short-Form 36 Health Survey  
**SNAP:** Study of Novel Approaches to Weight Gain Prevention  
**TG:** triacylglycerides  
**UIUC:** University of Illinois at Urbana-Champaign



**Figure 4.1.** Diagram of recruitment, enrollment and randomization of participants in a study examining weight gain prevention in young adult and midlife women.

**Table 4.1.** Baseline characteristics of women (n=81) participating in a 12-month weight gain prevention intervention and completing baseline testing.

<b>Characteristic</b>	<b>All participants mean (SD)</b>
Age (years)	31.4 (8.1)
Height (cm)	165.2 (5.9)
Weight (kg)	76.1 (19.0)
Body mass index (kg/m <sup>2</sup> )	27.9 (6.8)
Waist circumference (cm)	83.3 (13.6)
Hip circumference(cm)	110.7 (14.6)
Waist:hip ratio	0.8 (0.1)
Body fat (%)	34.6 (9.1)
Fat mass (kg)	27.9 (14.2)
Fat free mass (kg)	48.2 (5.4)
Systolic blood pressure (mm Hg)	106.2 (11.0)
Diastolic blood pressure (mm Hg)	70.9 (9.9)
Resting heart rate (bpm)	65.8 (6.0)

**Table 4.2.** Demographic and education characteristics of all women (n=81) randomized to all groups.

<b>Characteristic</b>	<b>All participants No. (%)</b>
<b>Education</b>	
High school graduate	2 (3)
Some college	15 (18)
2-year associate degree/graduate	2 (3)
4-year college degree/graduate	21 (26)
Some graduate school	8 (10)
Master’s degree	27 (33)
Doctorate degree	6 (7)
<b>Race/ethnicity</b>	
White, non-Hispanic	53 (66)
Black, non-Hispanic	10 (12)
Asian	8 (10)
Non-white Hispanic or Latino	4 (5)
Other (including multiracial)	6 (7)
<b>Total annual household income</b>	
<\$15,000	7 (9)
\$15,000 - \$49,999	30 (37)
\$50,000 – \$99,999	25 (31)
>\$100,000 – \$199,999	18 (22)
No response	1 (1)

## CHAPTER 5: Effect of nutrition education on weight gain prevention: a randomized controlled trial<sup>4</sup>

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### Abstract

**Background:** Body weight (BW) reduction through energy restriction is ineffective in impacting the obesity epidemic. Shifting from an obesity treatment to weight gain prevention or BW maintenance focus may be more effective in decreasing the burden of adult obesity.

**Methods:** This was a 1-year randomized controlled trial of weight gain prevention in healthy premenopausal women, aged 18-45 y, with a body mass index (BMI) of >18.5 kg/m<sup>2</sup>. Eighty-seven women were randomized to a weight gain prevention intervention delivered by a registered dietitian (RDG) or counselor (CSG), or to a control group (CON). Eighty-one women (mean±SD, age: 31.4±8.1 y; BW: 76.1±19.0 kg; BMI: 27.9±6.8 kg/m<sup>2</sup>) completed baseline testing and were included in intention-to-treat analyses; anthropometric, blood pressure, dietary intake and physical activity measurements and biochemical markers of health were measured every three months. Data were analyzed using repeated measures ANCOVA; significance was set at P<0.01.

**Results:** Sixty-two percent of these women met weight gain prevention criteria after one year (BW change ±3%); this did not differ by group assignment. Body fat percentage was significantly lower in the RDG versus CSG and CON groups at all intervals (P<0.001). Systolic blood pressure significantly changed over time in the CON group (P<0.001), with a significant group x time interaction (P<0.01). Fruit intake was significantly different between the RDG and CON groups at month 6 and 12 (both P<0.01). No significant group differences were observed for additional anthropometric measurements, resting heart rate, systolic and diastolic blood pressure, macronutrient intake, food groups, total energy expenditure or biochemical markers of health (all P>0.01). There were no significant time effects for any anthropometric measurements, resting heart rate, diastolic blood pressure, dietary intake, total energy expenditure or biochemical markers of health (all P>0.01).

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**Conclusions:** Although the effect of nutrition education on weight gain prevention was not significant, a majority of participants maintained BW over one year. Further monitoring may determine if nutrition education impacts BW regulation over the long term. Future interventions should continue to examine BW in addition to other clinical outcomes to assess overall health status.

**Key words:** body weight; obesity; overweight; weight gain prevention; weight loss; weight management; women



## Background

More than two-thirds of adults and nearly two-thirds of women in the United States remain overweight and obese, even as the prevalence of overweight and obesity has stabilized in recent years [1]. Energy restriction and other methods to induce body weight (BW) reduction are popular and widely promoted [2,3]. While a variety of approaches result in short-term weight loss success [4-11], none of these methods have significantly impacted the obesity epidemic by permanently reducing BW over the long term for a significant amount of people [2,4, 12-16]. In fact, among individuals who have achieved weight loss, most return to initial weight status within three to five years following weight loss [13-15], and one-third to two-thirds of these individuals will regain more weight than was initially lost [4]. Even individuals who undergo bariatric surgery gradually regain weight over time [17,18]. Therefore, new prevention or treatment efforts and solutions to reduce the burden of adult obesity are necessary.

One such alternative may be shifting from a weight loss treatment approach to a weight gain prevention and health promotion approach. Weight gain prevention may also be referred to as weight maintenance and literally implies no change in BW. Unlike weight loss which is relevant only for individuals with excess BW, weight gain prevention is relevant for individuals with normal weight, overweight or obesity to manage current diseases and related risk factors [19], prevent the development of metabolic abnormalities and prevent the progression to overweight and/or obesity [20]. While other health indicators may be improved with weight loss, these benefits may be mitigated with weight regain. However, positive behavior changes can result in similar improvements in health indicators such as blood pressure [20-24] and blood lipid levels [20,21,24-26], even in the absence of weight change.

Research examining weight gain prevention is limited [27-35], and study populations have differed by gender (female only or males and females) and BW status (normal weight only, normal and overweight, overweight and obese only). As determinants of weight gain prevention may differ between males and females [3,36-38], the current study aimed to identify determinants of weight gain prevention in premenopausal women participating in a 1-year randomized controlled trial of weight gain prevention that included nutrition education.

Women randomized to a nutrition education intervention group were hypothesized to maintain current BW, within  $\pm 3\%$  [39], over the 1-year intervention period as compared to a control group. Further, it was hypothesized that women randomized to a nutrition education group led by registered dietitians would have lesser weight gain over the 1-year intervention period as compared to women randomized to an identical nutrition education group led by counselors with no formal nutrition training.

## **Methods**

### ***Participants***

Premenopausal women with a body mass index (BMI) of  $>18.5 \text{ kg/m}^2$  and aged 18-45 years were recruited from the Urbana-Champaign communities and surrounding areas of Illinois. Full details regarding recruitment, screening and enrollment have been previously described along with complete inclusion and exclusion criteria [40]. Briefly, women were eligible to participate if they met age and BMI criteria and desired to prevent weight gain. Women were excluded if they were amenorrheic; presented with depressive symptomology as suggested by a score of  $>50$  on the Zung Self-Rating Depression Scale/Status Inventory [41]; self-reported cardiovascular, metabolic or musculoskeletal abnormalities or used medications to manage such conditions; used supplements and/or medications that may influence BW regulation; had undergone weight loss surgery; or were currently pregnant, lactating or planning to become pregnant.

The Institutional Review Board (IRB) for the Protection of Human Subjects at the University of Illinois at Urbana-Champaign approved the study protocol (IRB#14397). Each participant provided written informed consent prior to participating in the study.

### ***Study design and intervention***

This was a 1-year parallel-arm randomized controlled trial of weight gain prevention that was conducted between August 2014-August 2015. After enrollment, participants were randomly assigned to a control group (CON), a weight gain prevention intervention delivered by a registered dietitian (RDG), or a weight gain prevention intervention delivered by a counselor (CSG). The weight gain prevention interventions delivered to the RDG and CSG were identical in

content and materials, but differed in the credentialing of the group leader. Between August 2014-August 2015, women randomized to the CON received no intervention.

Full details of the intervention have been described elsewhere [40]. Women in the RDG and CSG attended a total of 24 nutrition education sessions over the course of the 1-year intervention period. All sessions were 1-hour in length and emphasized portion control, planning ahead and vegetable consumption [42,43]. For the first 16 weeks of the intervention (months 1-4), participants attended weekly sessions; for the remaining 8 months of the study (months 5-12), participants attended monthly sessions [44]. Weekly sessions focused on general nutrition education, while monthly sessions addressed other areas of lifestyle behavior such as stress management, problem solving and motivation [40,42-47]. Six session times were offered each week/month per group. Participants were permitted to attend the session day and time that worked best for them during the respective week/month. Dates, times and building location were matched between RDG and CSG to ensure all participants had the same opportunities to attend sessions.

Education sessions were randomly selected for process evaluation by one process observer, using investigator-established criteria to assess fidelity. The number of participants attending each session was recorded, as was the start and end time. The fidelity checklist included educator-oriented items along with content-related items. The process observer rated the educator using a 'yes/no' rating system on items such as preparedness, familiarity, accuracy and ability to respond appropriately to questions. A comment box was also used to note general feedback on these items as deemed relevant by the process observer. Content-related items addressed whether underlying key concepts (portion control, vegetable consumption, planning ahead) and problem solving were covered. The process observer also recorded comments regarding challenges or difficulties of the education sessions. These evaluations assessed whether content for each session was covered and delivered appropriately and that all session activities were completed.

Four female registered dietitians with <5 years of experience delivered the intervention to RDG participants. Four female graduate teaching assistants from the University of Illinois at Urbana-Champaign in programs not related to nutrition and dietetics delivered the intervention

to CSG participants. Counselors were trained by one registered dietitian, including a code of conduct, before the start of the intervention. At least one week in advance of each session, all leaders were provided with the PowerPoint slides and script that included directions for session activities. Counselors also met with the registered dietitian to receive a brief overview of session handouts and activities and to have any questions answered.

To eliminate the potential for leader bias or participant attachment to a particular dietitian or counselor, education leaders rotated through the class dates and times to ensure equal interactions between the participants in each group and each of the four respective group leaders. Compliance with the intervention was defined as attending >85% of education sessions. For women who could not attend an education session, a virtual make-up session, accompanied by a short quiz, was offered. Women were deemed compliant if the quiz was accurately completed and returned to the primary investigator. Women were not informed of the credentials of session leaders until completion of the 1-year intervention.

### ***Testing sessions***

During the 1-year intervention, women participated in testing sessions (between 7:00 and 9:30 AM) before the intervention (baseline) and at month 3, month 6, month 9 and month 12. Anthropometric measurements, blood pressure, physical activity and biochemical markers of health were collected and evaluated at each measurement interval. Dietary intake was evaluated at baseline, month 6 and month 12.

### ***Anthropometrics***

A calibrated scale-mounted stadiometer (Seca 700, Hanover, MD, USA) was used to measure standing height (cm). Body weight (BW;kg), fat mass (FM;kg) and body fat percentage (BF%) were measured using a calibrated scale (Tanita 410GS, Arlington Heights, IL, USA). Height and BW measurements were used to calculate BMI ( $\text{kg}/\text{m}^2$ ) for each participant. Two measurements each of waist circumference (cm) and hip circumference (cm) were taken to the nearest 0.1 cm using a retractable measuring tape (Gulik II, Country Technology, Inc, Gay Mills, WI) and averaged. Waist circumference was measured at the narrowest point of the waist, approximately one inch above the navel, and hip circumference was measured at the widest part of the buttocks [43]. Waist and hip circumference measurements were used to calculate

waist-to-hip ratio. One research team member conducted all height and BW measurements, and a second research team member performed all waist and hip circumference measurements.

### ***Blood pressure***

A trained study investigator measured seated systolic and diastolic blood pressure (mm Hg) using a standard sphygmomanometer (Baumanometer® Desk Model, Copiague, NY, USA). Two blood pressure readings were taken with a 2-3 minute rest period between readings; the average systolic arterial pressure and average diastolic arterial pressure were recorded. Resting heart rate was also measured by pulse palpitation following a 5-minute rest period.

### ***Dietary intake***

Four-day food records were used to estimate dietary intake. In the week before baseline, month 6 and month 12 testing sessions, participants recorded all foods and beverages, including portion sizes, consumed for three weekdays and one weekend day [40]. The Nutrition Data System for Research (NDSR) dietary analysis software (Nutrition Coordinating Center, Minneapolis, MN, USA) was used to analyze food records to estimate average daily intake of total energy (kcal/day), carbohydrate (g/day), protein (g/day), fat (g/day), fiber (g/day) and food groups (svgs/day).

### ***Physical activity***

The Stanford 7-Day Physical Activity Recall Scale [48] was used to estimate physical activity. For seven consecutive days before all testing sessions, participants recorded the number of hours spent engaged in moderate, hard, and very hard activities, screen time (television, computer) and hours slept [48]. Minutes of physical activity per day were estimated by summing total minutes of moderate, hard, and very hard activity and dividing by seven. Calories expended per day were estimated by converting activities into metabolic equivalents (METs; hr/d) [40,43].

### ***Biochemical markers of health***

Venous blood samples (~30 mL) were collected from each participant following a 12-hour fast. Samples were processed, and serum was stored at -80°C until completion of bioassays for

glucose, insulin, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), total cholesterol and triglycerides (TG).

Spectrophotometry was used to measure serum glucose (mg/dL), total cholesterol (mg/dL), HDL-C (mg/dL) and TG (mg/dL) concentrations (all Stanbio Labs Boerne, TX, USA). Total cholesterol, HDL-C and TG concentrations were used to calculate LDL-C concentration (mg/dL) using the equation:  $LDL-C = total\ cholesterol - HDL-C - (TG/5)$  [49]. Enzyme-linked immunosorbent assay (ELISA) was used to measure serum insulin ( $\mu U/mL$ ; LINCO Research, St Charles, MO, USA). All serum samples were analyzed in duplicate for each study interval. Intra-assay coefficients of variations (CV) for serum glucose, total cholesterol, HDL-C and TG were 5.2, 5.4, 4.9 and 7.2%, respectively.

### ***Statistical analyses***

Participants completing baseline testing (n=81) were included in the intention-to-treat analyses, and the last observation carried forward approach was employed. A secondary efficacy analysis of only study completers also was conducted (n=48). The three groups (RDG, CSG and CON) differed at baseline by age, BW and BMI; hence, these variables were entered as covariates in all analyses examining effects of intervention. A 3x5 (3 treatment groups x 5 time intervals) analysis of covariance (ANCOVA) with repeated measures on the time factor was used to assess differences in outcome measures between and within treatment groups. If sphericity was violated, the Greenhouse-Geisser correction was used. The interaction of group (treatment) x interval (time) was assessed if a main effect of group or time was detected. Bonferroni adjustments for multiple comparisons were completed when significant group, time or group x time interactions were found.

Before conducting data analyses, outliers were identified for each outcome variable using the outlier labeling rule [50,51] and excluded from all analyses specific to that variable. Data are presented as unadjusted means  $\pm$  standard deviation (SD) unless otherwise indicated. All data analyses were conducted using the Statistical Package for the Social Sciences (version 22.0, 2013, IBM Corp, Armonk, NY, USA). Statistical tests were two-sided, and significance was set at  $P < 0.01$ .

### **Results**

Figure 5.1 displays the flow diagram of enrollment and study completion of women in the current randomized controlled trial of weight gain prevention. Of the 330 women that responded to recruitment efforts between June-August 2014, 266 women met prescreening criteria and were sent additional screening materials and informed consent, which were returned by 146 women [40]. After review of materials by investigators, 102 women met eligibility criteria, and 97 of these women attended an informational session. Eighty-seven women were enrolled and randomized to the RDG (n=29), CSG (n=29) or CON (n=29) group. Baseline testing was completed by 81 healthy premenopausal women (White, non-Hispanic, n=53; Black, non-Hispanic, n=10; Asian, n=8; Non-white Hispanic or Latino, n=4; Other, including multiracial, n=6). Seventy-one women completed month 3 testing, 62 women completed month 6 testing, 60 women completed month 9 testing, and 48 women completed month 12 testing. The 81 women completing baseline testing (age: 31.4±8.1 y; BW: 76.1±19.0 kg; BMI: 27.9±6.8 kg/m<sup>2</sup>) were included in intention-to-treat analyses. Women who completed the intervention (n=48; age: 33.4±7.2 y; BW: 79.7±19.7 kg; BMI: 29.5±7.2 kg/m<sup>2</sup>) were significantly older (P<0.01) as compared to women who did not complete the intervention (n=33; age: 28.4±8.6 y; BW: 70.7±17.0 kg; BMI: 25.6±5.6 kg/m<sup>2</sup>). When controlling for baseline age, BW and BMI, group assignment did not have an effect on participant dropout (P>0.01).

### ***Weight gain prevention***

Approximately 62.0% of the original sample (n=50) and 56.3% of completers (n=27) maintained BW (±3%) over the intervention period. Using intention-to-treat analysis, 65.0% of the RDG (n=17), 65.5% of the CSG (n=19) and 53.8% of the CON (n=14) group met weight gain prevention criteria and were classified as successful. This distribution was similar among completers with 63.6% of the RDG (n=7), 56.3% of the CSG (n=9) and 52.4% of the CON (n=11) group meeting weight gain prevention criteria.

### ***Education session compliance and process observation***

Weekly, monthly and overall compliance did not differ by group assignment. Compliance was defined as attendance at >85% of education sessions (21/24 overall, 14/16 for weekly sessions, 7/8 for monthly sessions). Using this criteria, 88.6% (n=39) of women randomized to the RDG and CSG who were still enrolled after 16 weeks (n=44) were deemed

compliant with weekly attendance (RDG=20; CSG=19), and 81.5% (n=22) of the RDG and CSG who completed the intervention (n=27) were compliant with monthly attendance (RDG=10; CSG=12). Overall, 88.5% (n=23) of women who were randomized to the RDG and CSG and completed month 12 testing (n=27) were compliant (RDG=10; CSG=13).

Twenty-two RDG and 17 CSG education sessions were observed. On average, sessions lasted  $39.1 \pm 11.1$  min; however, RDG sessions were significantly longer than CSG sessions ( $43.3 \pm 9.2$  vs.  $33.5 \pm 11.2$  min,  $P < 0.01$ ). On average,  $2.9 \pm 1.6$  participants attended each session, and this did not differ between groups. Based on the fidelity checklist, participants in both groups were equally engaged in education sessions, and vegetable consumption, portion control and planning ahead for food intake were addressed equally across all sessions. The process observer perceived that the registered dietitians were more likely to give specific scenarios and reinforce points made in various education sessions than counselors. It was also perceived that counselors tended to read from the script, while registered dietitians were more familiar with the topics and able to discuss without relying on supporting materials.

### ***Anthropometric measurements***

There were no significant group differences for BW, BMI, FM, waist circumference, hip circumference or waist-to-hip ratio (Table 5.1). BF% was significantly lower in the RDG compared to the CSG and CON groups at all intervals. Women in all groups were able to prevent gains in BW, BMI, FM, BF%, waist circumference, hip circumference and waist-to-hip ratio over time, and there was no time effect for these anthropometric measurements. Results were similar with efficacy analysis; however, the P-value for group differences in BF% increased to  $P < 0.01$  ( $P < 0.001$  for intention-to-treat analysis; data not shown).

### ***Blood pressure***

Group assignment had no significant effect on resting heart rate, systolic blood pressure or diastolic blood pressure (Table 5.2). Significant changes in systolic blood pressure were observed over time within the CON group between month 6 and 9 and month 6 and 12. A significant group x time interaction was detected for systolic blood pressure [ $F(7.1, 264.5) = 2.7$ ,  $P < 0.01$ ] such that change within the CON group was significantly different from the RDG and CSG groups from month 6 to 9 and from month 6 to 12. The efficacy analysis revealed a



significant time difference ( $P < 0.01$ ) for the CON group between month 6 and month 9 (data not shown) which differed from the intention-to-treat analysis. Additionally, the group x time interaction for systolic blood pressure was no longer significant in the efficacy analysis.

### ***Dietary intake***

Dietary intake data are displayed in Table 5.3. Total energy intake, total and percent carbohydrate, total and percent protein, total and percent fat and total fiber did not differ significantly by group and did not significantly change over time. Servings of fruits, vegetables, whole and refined grains, lean meats and non-meat protein sources and low-fat and fat-free dairy did not change over time. Only fruit intake was significantly different between the RDG and CON at month 6 and 12. There was no group x time interaction for any food group servings, however. The efficacy analysis revealed no significant differences in macronutrient or food group serving intakes between groups or over time (data not shown).

### ***Physical activity***

Total energy expenditure did not significantly change over time and was not significantly different by group (Table 5.3). Results from the efficacy analysis were congruent with intention-to-treat findings (data not shown).

### ***Biochemical markers of health***

No significant group differences were observed for total cholesterol, HDL-C, LDL-C, TG, glucose or insulin concentrations and there were no significant changes for any of these biomarkers over time (Table 5.4). A group x time interaction was not found for any blood lipids, glucose or insulin concentrations. Similar results were found with the efficacy analysis (data not shown).

### **Discussion**

This randomized controlled trial aimed to prevent weight gain in healthy premenopausal women over one year and to compare the effects of an intervention delivered by a registered dietitian to a counselor on weight gain prevention in the same sample of women. Although women randomized to a nutrition education intervention were able to maintain BW within  $\pm 3\%$ , women who did not receive a nutrition education intervention also were able to maintain BW within  $\pm 3\%$ . Despite that neither hypothesis was supported, approximately 62% of women

enrolled in the study were able to maintain BW over the 1-year intervention. Further, more women in the RDG group (absolute BW change:  $1.4 \pm 2.9$  kg; relative BW change:  $0.79 \pm 1.6\%$ ) were successful in weight gain prevention as compared to CSG (absolute BW change:  $0.50 \pm 3.2$  kg; relative BW change:  $0.41 \pm 2.3\%$ ) and CON groups (absolute BW change:  $0.71 \pm 3.8$  kg; relative BW change:  $0.61 \pm 2.6\%$ ), though these differences were not significant. The average absolute and relative change in BW for the entire sample was  $0.85 \pm 3.3$  kg and  $0.61 \pm 2.6\%$ , respectively. The lack of differences between the three groups demonstrates that women can, in fact, successfully prevent weight gain over one year. However, a large proportion of the population still struggles with weight gain, and further evaluation is needed to have a significant impact on the current obesity epidemic in the United States.

Overall findings from this study related to changes in BW and weight gain prevention are consistent with those of Pound of Prevention [28,29], Levine and colleagues [30] and the Groningen Overweight and Lifestyle (GOAL) Study [31-33] which found interventions or treatments to have no significant effect on BW over time. In Pound of Prevention, a no-contact control group was compared to a group that received monthly nutrition education via newsletters and a group that received the same nutrition education plus lottery incentives for participation [28,29]. Over a 3-year period, weight gain did not differ significantly between groups [29], and mean BW change after one year in Pound of Prevention [28] was similar to that of the current study. Similarly, no effect on BW in normal weight and overweight women was observed by Levine and colleagues [30], who compared 15 group education sessions, 15 correspondence education lessons and an information-only control over three years. The GOAL Study randomized overweight and obese men and women with hypertension and/or dyslipidemia to receive usual care from a general practitioner or computer-guided lifestyle counseling from a nurse practitioner [31-33]. After one year, men randomized to the nurse practitioner group had a significantly greater weight change as compared to the usual care group [31], but these differences were not apparent after three years [33]. In women, there was no difference between the two groups at either one year [31,32] or three years [33].

When examining the prevalence of weight gain prevention or weight maintenance in the context of an entire population, it becomes somewhat problematic, as the definition of

weight maintenance has not been consistently used. Jeffery and French found that 37% of participants in Pound of Prevention maintained or lost weight, but investigators did not specify how “maintained” was defined [29]. A similar prevalence of weight gain prevention (40%) was found by Levine and colleagues [30], who defined maintenance as at or below  $\pm 2$  pounds of baseline weight. The GOAL Study found a prevalence of 71.4% and 62.7% at one [31] and three years [33], respectively, using a definition of  $< 1\%$  BW gain [31-33]. The 62% of women that were classified as successful at weight gain prevention in the current study may be slightly underestimated as women were only classified as weight maintainers if percent BW change was  $\pm 3\%$ ; therefore, women who lost  $> 3\%$  of BW were classified as non-weight maintainers.

Only two of the six previous studies that have examined weight gain prevention have been successful in preventing weight gain over time [27,34]; final results of the Study of Novel Approaches to Weight Gain Prevention (SNAP) are not yet available [35]. Age has been identified as a predictor of weight gain prevention [27,30] which may explain why a low-intensity nutrition education intervention via monthly newsletters was effective in producing a significantly greater BW change over one year when compared to a no-contact control in which the mean age of participants was 45.9 years [27]. The Shape Program [34] compared usual care to a primary care-based medium-intensity behavioral weight gain prevention intervention in premenopausal overweight and obese class 1 black women. Weight change was significantly larger in the intervention group compared to usual care at one year and 18 months; however, there were no differences between groups in any other outcome measures [34]. While findings of the Shape Program were significant, results are limited in generalizability due to race and socioeconomic status of the sample population.

The current randomized controlled trial of weight gain prevention builds upon the strengths and recommendations of previous weight gain prevention trials. The current trial was unique in that it included only women and did not exclude on the basis of BMI (except for underweight). Treatment had a greater effect on weight gain prevention after one year in men in A Pound of Prevention [27] and the GOAL Study [31-33] which suggests women may need different types or intensities of interventions. Both of these interventions [27,31-33] were relatively low in intensity, while the current trial was moderate in intensity. The nutrition

education component of the current intervention included group education classes, as previous research has demonstrated that group therapy results in greater weight loss when compared to individual therapy, even among individuals who prefer individual counseling [52]. Jeffery and French [29] previously recommended that more attention should be given to frequency of messages, interactive components and motivational concerns, all of which were addressed in the current randomized controlled trial of weight gain prevention in women.

With further regard to the nutrition education component of the intervention, this is the first trial to test a weight gain prevention nutrition education intervention delivered by a registered dietitian compared to an individual without formal nutrition training. The absence of differences in main outcomes between the RDG and CSG suggests that the two interventions were equally effective in promoting weight gain prevention in this sample of healthy premenopausal women. Similar findings related to the use of peer or lay educators have been observed in programs and interventions aimed at reducing chronic disease risk factors [53-57]. Although it was hypothesized that the RDG would have less weight gain over time due to the specialized training of registered dietitians, the counselors were trained by a registered dietitian and received all lesson slides and materials, including scripts. These findings are similar to those of Katula and colleagues in which community health workers trained and supported by registered dietitians delivered a 24-month lifestyle intervention that resulted in significant reductions in BW, BMI, waist circumference, glucose, insulin and insulin resistance in individuals with pre-diabetes [55]. When provided with adequate training by registered dietitians, lay educators may be able to promote outcomes equal to those of registered dietitians. These findings present an opportunity for registered dietitians to expand their sphere of influence by training and supporting lay educators to have an impact on health promotion by providing accurate and credible information. By training these individuals, registered dietitians can help reduce the amount of nutrition misinformation that these individuals may otherwise communicate with the public.

As a focus on weight and weight loss has not produced positive long-term results in reducing the obesity epidemic, a continued focus on weight as the primary indicator of health may cause more harm than good by increasing preoccupation with food, increasing the

likelihood of weight cycling and decreasing body image and self-esteem [2]. Therefore, collecting and examining other indicators of health, beyond BW and anthropometrics, is warranted. Weight is one component of metabolic health [58,59] and other indicators of metabolic health should be considered when assessing overall health status. Even in this sample of women who were overweight, on average, blood pressure, lipid levels and glucose were within normal ranges. Further, lifestyle and behavior changes can positively improve clinical health indicators, even in the absence of weight change [20-26]. Using only BW or BMI as proxies for health may misidentify healthy overweight and obese individuals as unhealthy and in need of treatment and unhealthy normal weight individuals as healthy and not in need of treatment [2,58,59]. Both of these situations may translate into increased healthcare costs through unnecessary treatment or worsening of conditions that were not identified due to the use of BW or BMI as the primary indicators of health. The current trial is one of the few studies to collect clinical health indicators beyond BW and anthropometrics in addition to questionnaires assessing health behaviors and psychosocial outcomes. Even though there were no significant findings with regards to other indicators of health, the current study provides an example for future interventions.

While the findings of the current study do not support the *a priori* hypotheses, there are several explanations for these findings. Weight changes over the course of one year were expected to be relatively small, so the absence of a stronger effect of the nutrition education weight gain prevention intervention is not entirely surprising. As a majority of women in the RDG and CSG successfully prevented weight gain over one year, this is promising that nutrition education may play a role in weight gain prevention over the long term. Further, similar to Wong and colleagues [60] baseline indicators of health were not clinically abnormal in this population of women. Therefore, lifestyle and behavior changes made during the intervention period, while positive, may not have been large enough to produce a substantial impact [60]. Over time, these sustained lifestyle and behavior changes may result in more clinically meaningful improvements.

The lack of statistically significant findings also may be explained by the Hawthorne effect or observation bias [61]. Even though women in the CON group did not receive any

intervention or information, their BW was assessed, along with a variety of other outcome measures at the same intervals as women receiving the nutrition education intervention. The Hawthorne effect may have resulted in CON participants modifying or altering behavior more so than under different circumstances, which may explain why there were no differences observed between the RDG and CSG compared to the CON. Additionally, women who enrolled in the study may have had more motivation to make lifestyle and behavior changes than individuals who were eligible and chose not to participate. Individuals who may benefit most from this type of intervention may not be adequately represented due to volunteer or self-selection bias [62].

Another explanation for non-significant findings may be the purposeful rotation of education leaders across education sessions. Providing exposure to multiple educators (i.e., four each) within the specified RDG or CSG group was done to specifically minimize potential effects of a particular educator on participant outcomes resulting from educator-participant bonding or external responsibility or support [63] rather than the intervention itself.

The inclusion of free-living women in this weight gain prevention intervention is a major strength of the current study, and findings from this study may be generalizable to similar populations of women with a desire to prevent weight gain. The nutrition education component of this intervention not only provided credible nutrition information, but also accountability and group support, all of which have been identified as facilitators to weight loss and weight loss maintenance [3]. Further, a majority of participants were compliant, indicating this was a feasible intervention with high participation. Although overall participant attrition was high at the conclusion of the intervention, nearly 75% of the original sample remained through month 9 of the study, indicating that the intervention was realistic for free-living individuals.

This study is not without limitations. As previously mentioned, the final retention rate was moderate which limits statistical power of the study; results should be interpreted with caution. However, a majority of individuals moved away from the area in the final month of the study and were unable to attend the final testing session. These “dropouts” were much different than the women who chose to withdraw from the study for other reasons. While the

use of free-living women was a strength, it was also a weakness as it is difficult to fully assess dietary intake and physical activity due to the limitations of self-report. Further, results from this study are only generalizable to women similar to those included in this study. More research is needed to target women of a wider range of ethnicities. Future research should also examine weight gain prevention in men of this same age range, as well as postmenopausal women.

### **Conclusions**

In conclusion, while this randomized controlled trial of weight gain prevention did promote weight maintenance in a sample of healthy premenopausal women, there were no differences between women who received the weight gain prevention intervention compared to those randomized to a control group. Non-significant findings demonstrate that weight gain prevention over one year is possible; however, longer follow up periods are necessary. Clinically meaningful or significant benefits of participation in this study may become apparent over time, but long-term follow up data are not available. As weight loss and weight loss maintenance remain a challenge for much of the population, future interventions should focus on indicators of health in addition to BW and utilize a health promotion and weight gain prevention approach.

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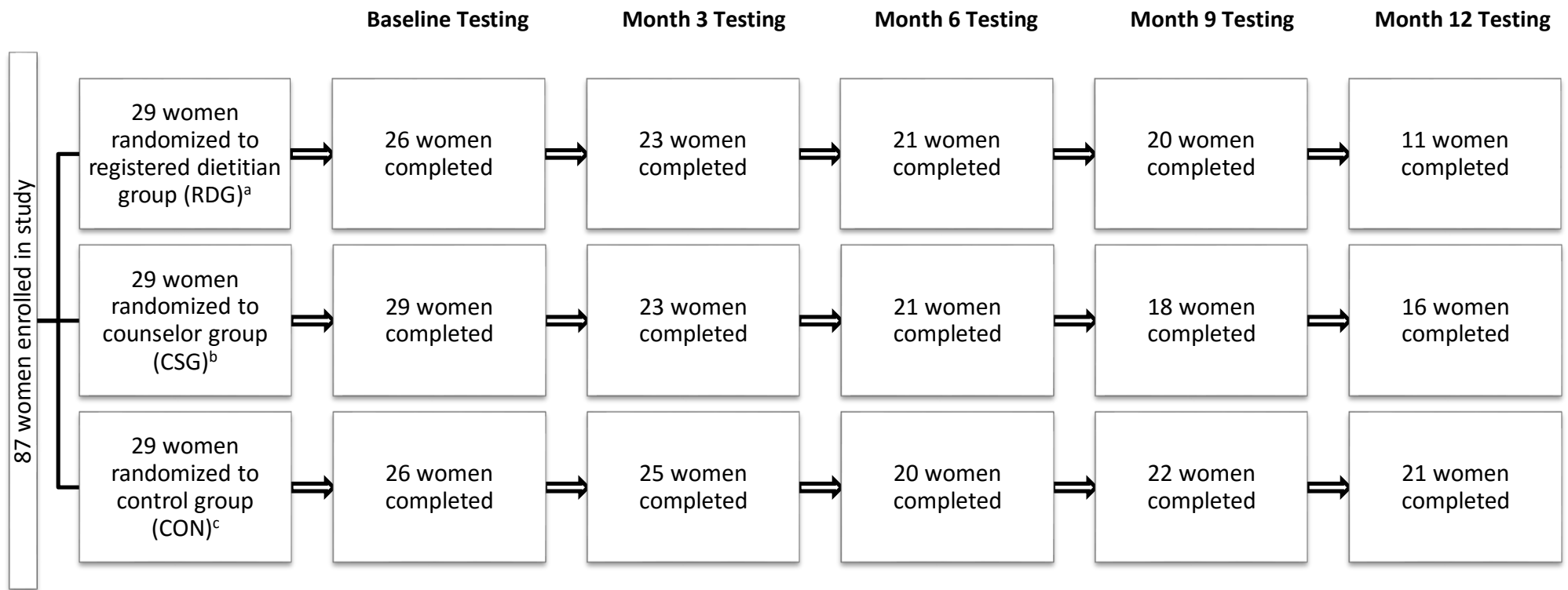
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**Figure 5.1.** Flow diagram of participant enrollment and completion of a 1-year randomized controlled trial of weight gain prevention in which women were randomized to a registered dietitian-led nutrition education group (RDG), a counselor-led nutrition education group (CSG) or a control group (CON).

RDG=registered dietitian group; CSG=counselor group; CON=control group.

<sup>a</sup>Reasons for withdrawal in RDG: time (n=2 before month 3 testing), family emergency (n=1 before baseline testing, n=1 before month 3 testing, n=2 before month 12 testing), moved out of the area (n=6 before month 12 testing), pregnancy (n=1 before month 9 testing, n=1 before month 12 testing), lost to follow up (n=2 before baseline testing, n=1 before month 6 testing, n=1 before month 12 testing); 1 participant in the RDG did not attend the month 6 testing session due to a family emergency, but completed all remaining testing sessions; 1 participant in the RDG did not attend the month 9 testing session due to a family emergency, but completed all remaining testing sessions.

<sup>b</sup>Reasons for withdrawal in CSG: uncomfortable with study (n=1 before month 3 testing), lost to follow up (n=1 before month 6 testing, n=1 before month 12 testing), moved out of the area (n=1 before month 9 testing, n=2 before month 12 testing), time (n=4 before month 3 testing), undisclosed (n=1 before month 3 testing), personal health issues (n=1 before month 9 testing), Zung >50 (n=1 before month 12 testing).

<sup>c</sup>Reasons for withdrawal in CON: time (n=3 before baseline testing, n=1 before month 3 testing), Zung >50 (n=1 before month 6 testing), moved out of the area (n=1 before month 12 testing), family issues (n=1 before month 12 testing), pregnancy (n=1 before month 6 testing); 3 participants in the CON did not attend month 9 testing (illness n=2, time n=1), but returned for month 12 testing.

**Table 5.1.** Anthropometric measurements of premenopausal women in a 1-year randomized controlled trial of weight gain prevention in which women were randomized to a registered dietitian-led nutrition education group (RDG), a counselor-led nutrition education group (CSG) or a control group (CON).

Variable	Group	Baseline	Month 3	Month 6	Month 9	Month 12	P-value
		← Mean ± standard deviation →					
Body weight (kg)	RDG (n=26)	59.8±6.5	60.2±6.5	60.5±6.8	60.8±6.6	60.6±6.6	Group = NS
	CSG (n=29)	71.1±7.6	71.3±7.6	71.8±7.9	71.6±8.1	71.8±8.7	Time = NS
	CON (n=25)	96.1±14.0	95.3±14.3	95.3±14.9	95.7±14.8	96.1±15.1	G x T = NS
Body mass index (kg/m <sup>2</sup> )	RDG (n=26)	21.7±1.5	21.8±1.5	21.9±1.6	22.1±1.5	22.0±1.5	Group = NS
	CSG (n=29)	26.3±1.9	26.4±2.1	26.6±2.3	26.5±2.3	26.6±2.6	Time = NS
	CON (n=25)	35.2±5.4	35.0±5.6	34.9±5.7	35.0±5.6	35.2±5.8	G x T = NS
Fat mass (kg)	RDG (n=26)	15.4±4.5	16.0±4.5	16.5±4.7	16.5±4.7	16.3±4.5	Group = NS
	CSG (n=29)	24.2±5.3	25.0±5.6	25.3±6.0	25.0±6.1	25.3±6.6	Time = NS
	CON (n=25)	43.3±9.8	43.6±10.6	43.6±10.6	43.8±10.8	43.9±10.7	G x T = NS
Body fat percentage (%)	RDG (n=26)	25.3±5.4	26.1±5.2	26.1±6.2	26.7±5.3	26.6±4.9	Group <0.001
	CSG (n=29)	33.7±4.3†	34.6±4.2†	34.8±4.8†	34.5±5.0†	34.7±5.1†	Time = NS
	CON (n=25)	44.6±3.9†	45.2±4.2†	45.2±4.8†	45.1±5.0†	45.3±4.2†	G x T = NS
Waist circumference (cm)	RDG (n=26)	70.8±4.5	70.7±4.7	70.8±4.4	70.6±4.5	70.8±4.4	Group = NS
	CSG (n=29)	80.3±5.0	80.1±5.0	80.5±5.0	80.2±5.4	80.5±5.6	Time = NS
	CON (n=25)	98.1±10.2	96.9±10.2	96.0±10.2	96.1±10.4	97.5±10.7	G x T = NS
Hip circumference (cm)	RDG (n=26)	97.4±4.7	99.4±3.8	100.0±4.3	99.0±3.6	98.7±4.2	Group = NS
	CSG (n=29)	108.0±6.5	108.2±5.5	108.0±5.7	107.3±5.8	107.4±6.0	Time = NS
	CON (n=24)	124.3±10.2	124.3±10.2	123.9±9.4	123.0±9.9	123.8±10.6	G x T = NS
Waist-to-hip ratio	RDG (n=26)	0.73±0.04	0.71±0.04	0.71±0.04	0.71±0.04	0.72±0.04	Group = NS
	CSG (n=29)	0.75±0.05	0.74±0.05	0.75±0.05	0.75±0.05	0.75±0.05	Time = NS
	CON (n=25)	0.78±0.07	0.78±0.06	0.78±0.06	0.78±0.07	0.78±0.06	G x T = NS

P-values using analysis of covariance, adjusted for baseline age, body weight and body mass index, with repeated measures on the time factor, using P<0.01 for statistical significance; data presented as unadjusted means ± standard deviation.

†different from RDG.

G x T = group x time interaction.

**Table 5.2.** Resting heart rate and blood pressure measurements of premenopausal women in a 1-year randomized controlled trial of weight gain prevention in which women were randomized to a registered dietitian-led nutrition education group (RDG), a counselor-led nutrition education group (CSG) or a control group (CON).

Variable	Group	Baseline	Month 3	Month 6	Month 9	Month 12	P-value
		←————— Mean ± standard deviation —————→					
Resting heart rate (bpm)	RDG (n=23)	64.0±2.8	68.3±9.5	65.7±7.6	63.1±8.3	61.8±6.1	Group = NS
	CSG (n=22)	65.1±2.1	64.9±8.4	62.5±6.3	62.9±6.2	61.4±4.1	Time = NS
	CON (n=20)	65.4±2.0	64.2±9.9	66.9±4.9	67.5±6.7	62.1±5.9	G x T = NS
Resting systolic blood pressure (mm Hg)	RDG (n=26)	100.4±7.0	99.6±7.7	100.5±6.8	99.3±5.9	100.0±5.7	Group = NS
	CSG (n=29)	107.8±9.8	106.3±10.3	107.5±9.9	105.8±11.0	105.2±10.5	Time <0.001
	CON (n=25)	110.5±13.4	110.8±10.6	111.8±8.7	108.6±9.1 <sup>a</sup>	108.4±9.1 <sup>a</sup>	G x T <0.01
Resting diastolic blood pressure (mm Hg)	RDG (n=26)	65.2±10.0	64.2±6.4	60.5±9.1	62.2±6.2	61.9±6.6	Group = NS
	CSG (n=29)	72.6±7.5	69.5±9.3	67.7±8.4	67.3±7.9	67.1±8.5	Time = NS
	CON (n=25)	74.9±10.2	70.8±8.7	67.2±8.4	67.4±8.3	68.7±8.1	G x T = NS

P-values using analysis of covariance, adjusted for baseline age, body weight and body mass index, with repeated measures on the time factor, using P<0.01 for statistical significance; data presented as unadjusted means ± standard deviation.

<sup>a</sup>different from Month 6.

G x T = group x time interaction.



**Table 5.3.** Macronutrient and food group intakes and energy expenditure of premenopausal women in a 1-year randomized controlled trial of weight gain prevention in which women were randomized to a registered dietitian-led nutrition education group (RDG), a counselor-led nutrition education group (CSG) or a control group (CON).

Variable	Group	Baseline	Month 3	Month 6	Month 9	Month 12	P-value
		← Mean ± standard deviation →					
Energy intake (kcal/d)	RDG (n=26)	1798.2±729.7		1682.7±595.5		1607.8±533.9	Group = NS
	CSG (n=29)	1971.7±604.7		1802.2±646.2		1837.6±656.5	Time = NS
	CON (n=26)	1795.9±707.8		1619.2±640.1		1709.7±719.0	G x T = NS
Total carbohydrate (g/d)	RDG (n=26)	219.6±106.0		202.9±81.4		186.7±68.6	Group = NS
	CSG (n=29)	214.2±82.2		216.4±89.8		218.4±93.9	Time = NS
	CON (n=26)	204.0±84.0		179.4±75.2		193.4±87.0	G x T = NS
Total protein (g/d)	RDG (n=26)	72.1±32.2		72.2±30.7		69.1±28.4	Group = NS
	CSG (n=29)	69.7±27.3		72.6±27.6		74.7±28.8	Time = NS
	CON (n=26)	74.0±38.6		70.9±33.4		72.1±34.2	G x T = NS
Total fat (g/d)	RDG (n=26)	71.5±36.9		66.4±33.1		66.1±32.0	Group = NS
	CSG (n=29)	73.1±34.7		71.8±32.7		71.8±30.5	Time = NS
	CON (n=26)	76.1±38.9		69.9±34.9		72.6±36.8	G x T = NS
Total fiber (g/d)	RDG (n=26)	19.0±11.8		19.6±9.2		16.9±7.1	Group = NS
	CSG (n=29)	19.3±11.3		19.9±11.3		18.4±9.8	Time = NS
	CON (n=26)	17.4±8.4		18.3±9.3		17.8±9.5	G x T = NS
Percentage carbohydrate (%kcal/d)	RDG (n=26)	48.1±11.3		47.5±11.1		46.0±11.0	Group = NS
	CSG (n=29)	47.4±11.2		47.0±10.0		46.3±9.3	Time = NS
	CON (n=26)	45.5±11.5		44.1±10.7		44.5±10.5	G x T = NS
Percentage protein (%kcal/d)	RDG (n=26)	16.5±6.4		17.6±6.6		17.7±7.0	Group = NS
	CSG (n=29)	15.8±5.2		16.6±5.1		16.7±4.8	Time = NS
	CON (n=26)	16.6±5.6		17.7±6.0		17.3±5.7	G x T = NS
Percentage fat (%kcal/d)	RDG (n=26)	33.9±9.0		33.8±8.7		35.2±8.5	Group = NS
	CSG (n=29)	35.1±8.9		34.9±8.4		34.6±8.6	Time = NS
	CON (n=26)	36.5±9.2		36.8±9.0		36.9±8.7	G x T = NS

**Table 5.3 (cont.)**

Fruit (svgs/d)	RDG (n=26)	1.9±2.3		2.1±2.3		2.0±2.7	Group <0.01
	CSG (n=29)	1.4±1.8		1.4±1.8		1.4±2.2	Time = NS
	CON (n=26)	1.6±2.2		1.1±1.4†		1.3±1.5†	G x T = NS
Vegetables (svgs/d)	RDG (n=26)	3.4±2.7		3.3±2.5		3.4±2.8	Group = NS
	CSG (n=29)	3.3±2.7		3.3±2.4		3.1±2.3	Time = NS
	CON (n=26)	3.3±2.3		3.3±2.4		3.4±2.4	G x T = NS
Whole grains (svgs/d)	RDG (n=26)	1.7±2.8		1.6±1.4		1.4±1.4	Group = NS
	CSG (n=29)	1.8±2.2		1.7±1.9		1.6±1.9	Time = NS
	CON (n=26)	1.8±1.8		1.7±1.9		1.8±2.0	G x T = NS
Refined grains (svgs/d)	RDG (n=26)	3.9±2.9		3.6±3.2		3.4±3.1	Group = NS
	CSG (n=29)	4.4±3.1		4.3±2.9		4.6±3.2	Time = NS
	CON (n=26)	4.1±3.6		3.3±3.0		3.8±3.3	G x T = NS
Lean meats (svgs/d)	RDG (n=26)	1.7±2.7		2.1±2.6		2.1±2.8	Group = NS
	CSG (n=29)	1.4±2.3		1.7±2.5		2.0±2.7	Time = NS
	CON (n=26)	1.8±2.7		1.7±2.3		1.9±2.6	G x T = NS
Non-meat protein sources (svgs/d)	RDG (n=26)	1.7±2.7		2.3±3.3		1.8±2.3	Group = NS
	CSG (n=29)	1.5±2.7		1.4±2.3		1.1±1.6	Time = NS
	CON (n=26)	1.3±1.9		1.5±2.0		1.3±1.9	G x T = NS
Low-fat and fat-free dairy (svg/d)	RDG (n=26)	0.54±0.68		0.80±0.97		0.71±0.85	Group = NS
	CSG (n=29)	0.79±0.95		0.83±1.1		0.86±0.94	Time = NS
	CON (n=26)	0.68±0.87		0.65±0.92		0.64±0.94	G x T = NS
Energy expenditure (kcal/d)	RDG (n=26)	1062.5±462.2	1002.2±411.4	1001.8±412.8	966.6±405.6	1009.2±389.2	Group = NS
	CSG (n=27)	1132.0±430.6	1003.1±341.3	978.2±330.4	1049.4±352.3	1069.1±354.8	Time = NS
	CON (n=21)	1322.2±489.6	1386.7±515.2	1330.1±561.7	1267.2±336.5	1302.9±371.4	G x T = NS

P-values using analysis of covariance, adjusted for baseline age, body weight and body mass index, with repeated measures on the time factor, using P<0.01 for statistical significance; data presented as unadjusted means ± standard deviation.

†different from RDG.

G x T = group x time interaction.

**Table 5.4.** Blood lipid, glucose and insulin concentrations in premenopausal women in a 1-year randomized controlled trial of weight gain prevention in which women were randomized to a registered dietitian-led nutrition education group (RDG), a counselor-led nutrition education group (CSG) or a control group (CON).

Variable	Group	Baseline	Month 3	Month 6	Month 9	Month 12	P-value
		←————— Mean ± standard deviation —————→					
Total cholesterol (mg/dL)	RDG (n=26)	165.6±28.8	172.1±28.9	173.5±28.7	177.1±26.3	169.9±23.7	Group = NS
	CSG (n=28)	163.7±32.9	176.8±36.1	174.5±32.7	178.2±35.3	176.0±32.3	Time = NS
	CON (n=24)	159.2±30.4	171.9±32.9	175.7±30.1	178.5±30.2	167.1±32.7	G x T = NS
High-density lipoprotein cholesterol (mg/dL)	RDG (n=26)	55.6±15.8	55.2±13.6	52.8±13.5	54.4±14.6	53.1±15.3	Group = NS
	CSG (n=29)	52.7±12.1	52.3±12.8	52.1±11.9	52.3±12.5	51.3±12.2	Time = NS
	CON (n=24)	44.3±10.0	44.0±10.7	45.7±9.5	47.0±10.2	45.9±11.1	G x T = NS
Low-density lipoprotein cholesterol (mg/dL)	RDG (n=26)	97.3±24.8	105.4±22.1	109.2±23.7	111.2±26.0	104.3±20.9	Group = NS
	CSG (n=28)	98.1±26.8	111.6±30.1	108.7±27.4	112.6±30.5	111.9±27.6	Time = NS
	CON (n=23)	93.6±21.5	109.5±21.8	112.9±21.8	111.3±22.8	100.7±22.0	G x T = NS
Triglycerides (mg/dL)	RDG (n=25)	58.6±28.1	53.6±26.9	56.0±25.1	55.7±24.5	57.1±22.3	Group = NS
	CSG (n=28)	66.9±29.0	63.8±25.3	65.3±27.4	68.4±32.2	67.2±34.2	Time = NS
	CON (n=22)	78.3±33.0	65.9±25.2	62.1±21.6	78.8±29.0	78.9±24.9	G x T = NS
Glucose (mg/dL)	RDG (n=23)	84.2±11.8	79.2±22.9	91.6±6.8	91.8±8.9	89.6±9.4	Group = NS
	CSG (n=25)	87.6±19.2	86.0±18.3	92.6±8.1	92.1±7.7	91.4±8.5	Time = NS
	CON (n=23)	88.2±11.9	85.5±21.9	92.0±7.5	93.6±12.9	91.7±8.4	G x T = NS
Insulin (μU/mL)	RDG (n=25)	3.4±1.6	4.6±3.4	4.3±3.0	3.8±2.0	3.6±1.7	Group = NS
	CSG (n=28)	4.8±2.2	5.6±2.1	5.0±1.9	5.1±2.1	5.0±2.4	Time = NS
	CON (n=21)	6.9±2.9	7.4±3.4	6.6±2.3	7.1±2.8	7.3±2.9	G x T = NS

Fasting serum used to measure all biomarker concentrations.

P-values using analysis of covariance, adjusted for baseline age, body weight and body mass index, with repeated measures on the time factor, using P<0.01 for statistical significance; data presented as unadjusted means ± standard deviation.

G x T = group x time interaction.

**ABSTRACT**

**OBJECTIVE:** The aim of this cross-sectional study was to explore the association between grit and cognitive eating restraint (CER), disinhibition and hunger and body mass.

**METHODS:** Seventy-nine women [mean±SD, age: 31.5±8.2 y, body weight (BW): 76.3±19.2 kg, body mass index (BMI): 28.0±6.9 kg/m<sup>2</sup>] completed the Short Grit Scale (Grit-S) and Eating Inventory (EI) upon enrolling in a 1-year weight gain prevention trial.

**RESULTS:** The average Grit-S score was 3.4±0.7. Average EI scores for CER (21 items), disinhibition (16 items) and hunger (14 items) were 9.1±3.5, 7.6±3.2 and 5.6±2.8, respectively. Grit-S score was negatively associated with disinhibition score ( $r=-0.47$ ,  $P<0.01$ ), hunger score ( $r=-0.19$ ,  $P=0.05$ ), BW ( $r=-0.24$ ,  $P<0.05$ ) and BMI ( $r=-0.23$ ,  $P<0.05$ ) and positively related to CER score ( $r=0.23$ ,  $P<0.05$ ). Disinhibition was the only predictor of BW ( $F=8.02$ ,  $P<0.01$ ) and BMI ( $F=7.05$ ,  $P=0.01$ ).

**CONCLUSIONS:** Women with more grit may have better weight management control as reflected by lower disinhibition and hunger scores and higher CER scores, as well as lower BW and BMI. Disinhibition, a cognitive disposition, may inversely reflect grit, a non-cognitive personality trait, to benefit BW and BMI; however, this requires further evaluation. Additional research is warranted to more fully understand grit in relation to other eating behavior traits in BW regulation.

**KEYWORDS:** Eating behaviors; Grit; Obesity; Weight management; Women

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<sup>5</sup>To be submitted to *Obesity Facts*.

## INTRODUCTION

Influenced by a multitude of factors at the individual, interpersonal, community, institutional and environmental levels, weight management is the result of complex interactions [1] and remains a challenge for many individuals. A more complete understanding of individual factors, including certain personality traits, may help nutrition professionals more fully support individuals in achieving weight management goals.

Grit – the perseverance and passion for sustaining efforts to pursue goals over time – may be one non-cognitive personality trait worth exploring in the field of weight management. While grit has not yet been examined in the context of weight management, previous studies show that grit is an indicator of success in life commitments, including scholarly pursuits [2-4], work efforts [4], military achievement [2,4], and marriage [4]. Among medical surgery residents, grit is a predictor of sound psychological health [5], and low grit may be a risk factor for withdrawal from surgical residency [6]. Further, grit is positively associated with high- and moderate-intensity exercise participation, as evaluated by stages of change in university students, faculty and staff [7].

Grit may be related to body weight (BW) regulation via cognitive control of food intake as cognitive eating restraint (CER), disinhibition and hunger are three eating behaviors associated with BW [8-12]. Cognitive eating restraint is defined as the tendency of some individuals to consciously limit food intake to manage body weight [8], disinhibition as the tendency of some individuals to overconsume food(s) in times of emotional distress [9], and hunger as the intensity and susceptibility to signs and symptoms related to food intake [9]. Though independent effects of CER, disinhibition and hunger on anthropometric measures are unclear, the interaction among these eating behaviors may be a useful predictor of BW status. Cognitive control of eating is essential to management and regulation of BW [8-14].

The current study explored the relationship between grit and CER, disinhibition and hunger (eating behaviors) and BW and body mass index (BMI) in a sample of adult women upon enrollment in a 1-year weight gain prevention trial. Based on grit as an indicator of perseverance, it was hypothesized that grit would be negatively associated with disinhibition

and hunger, BW and BMI and positively related to CER. It was also hypothesized that grit would predict body mass in this cross-sectional analysis.

## **METHODS**

### **Participants**

Premenopausal women, aged 18-45 y with BMI of  $>18.5 \text{ kg/m}^2$ , were recruited from the Urbana-Champaign (IL, USA) communities. Full recruitment, screening and enrollment details have been described elsewhere [15]. Briefly, screening criteria included appropriate age, BMI  $>18.5 \text{ kg/m}^2$  and desire to prevent weight gain. Inclusion criteria included: eumenorrhea ( $\geq 8$  menstrual cycles/y); absence of depressive symptomology as indicated by a score of  $<50$  on Zung Self-Rating Depression Scale/Status Inventory [16]; absence of metabolic, cardiovascular or musculoskeletal abnormalities and no use of medications to manage these conditions or medications or supplements influencing BW regulation; non-smoker; non-pregnant, non-lactating and no plans to become pregnant; and no history of weight-loss surgery.

The Institutional Review Board (IRB) for the Protection of Human Subjects at the University of Illinois at Urbana-Champaign approved the study protocol (IRB#14397). Each participant provided written informed consent.

### **Measurements**

Before the intervention (baseline), women completed self-administered paper-based questionnaires. Trained investigators collected anthropometric measurements from participants.

#### *Grit*

The Short Grit Scale (Grit-S), an 8-item questionnaire, was used to measure grit [3]. Using a 5-point (1=strongly disagree to 5=strongly agree) scale per item, women rated statements such as “I often set a goal but later choose to pursue a different one” [3] and “I finish whatever I begin” [3]. Items were averaged to produce an overall Grit-S score for each woman; possible scores ranged from 1-5 with higher scores indicating greater grit. Previous studies have found good internal reliability ranging from 0.73 to 0.84 [3,4,17,18].

### *Eating behaviors*

Ratings of CER, disinhibition and hunger were measured using the Eating Inventory (EI) [8], a 51-item questionnaire. Subscale scores for each construct were calculated using standard scoring methods [8], with possible scores ranging from 0-21, 0-16 and 0-14 for CER, disinhibition and hunger, respectively. Higher scores within each subscale reflect higher levels of the respective construct.

### *Anthropometric measurements*

Body weight (to the nearest 0.1 kg) and standing height (to the nearest 0.1 cm) were measured using a calibrated scale (Tanita 410GS, Arlington Heights, IL, USA) and stadiometer (Seca 700, Hanover, MD, USA), respectively. Investigators used these measurements to calculate BMI ( $\text{kg}/\text{m}^2$ ).

### **Statistical Analyses**

Descriptive statistics (means $\pm$ SD) were used to describe participant characteristics. Pearson's correlation coefficients were used to examine the relationship between Grit-S score and BW, BMI and CER, disinhibition and hunger scores. Backward elimination regression was used to further evaluate predictor variables of BW and BMI. The Statistical Package for the Social Sciences (version 22.0, 2013, IBM Corp, Armonk, NY, USA) was used to conduct all statistical analyses. Significance was set at  $P < 0.05$ .

### **RESULTS**

Seventy-nine of 81 participants (97.5%) provided complete questionnaires and were included in analyses. Women (age:  $31.5 \pm 8.2$  y) self-identified as primarily white, non-Hispanic ( $n=53$ , 67%), with at least a college degree ( $n=60$ , 76%) and middle to upper-middle income ( $n=43$ , 54%). Participants were overweight, on average (height:  $165.1 \pm 5.9$  cm, weight:  $76.3 \pm 19.2$  kg, BMI:  $28.0 \pm 6.9$   $\text{kg}/\text{m}^2$ ).

The average Grit-S score was  $3.4 \pm 0.7$  (range 2.0-4.6). Average scores (ranges) for CER, disinhibition and hunger were  $9.1 \pm 3.5$  (2-17),  $7.6 \pm 3.2$  (1-14) and  $5.6 \pm 2.8$  (0-13), respectively. Grit-S score was negatively related to disinhibition score ( $r = -0.47$ ,  $P < 0.001$ ), hunger score ( $r = -$

0.19,  $P=0.05$ ), BW ( $r=-0.24$ ,  $P<0.05$ ) and BMI ( $r=-0.23$ ,  $P<0.05$ ) and positively associated with CER score ( $r=0.23$ ,  $P<0.05$ ).

Together, Grit-S and disinhibition scores explained approximately 8% of the variability in BW and 7% of the variability in BMI. However, of the variables examined, disinhibition was the only significant predictor of BW and BMI in this sample of women (Table 6.1).

## DISCUSSION

The purpose of this study was to cross-sectionally explore the association between grit and eating behaviors and body mass in premenopausal women who enrolled in a 1-year weight gain prevention intervention [15]. The first hypothesis was supported in that women with higher grit had lower disinhibition and hunger scores and BW and BMI, along with higher CER score. Grit was not found to be a significant predictor of BW or BMI. To our knowledge, this is the first study to examine the relationship between grit and eating behaviors known to influence body mass status.

The mean Grit-S score of women in the current study ( $3.4\pm0.7$ ) is comparable to previous studies which have reported mean scores ranging from  $2.8\pm0.7$  to  $3.7\pm0.7$  in adult populations [2,5,18]. Thus, grit among the current sample of women is likely representative of other adult women.

Grit is a non-cognitive personality trait that has been shown to predict success or commitment in various life settings [2-7]. Similarly, individuals with higher grit may have the propensity for greater BW control, as they may better maintain effort and interest in weight management activities, even during setbacks (e.g., minor weight gain) [2-7] or challenges (e.g., in the presence of food/diet saboteurs). Though high CER has inconsistently been linked to lower BW, more highly restrained individuals tend to have lower energy and overall food intakes compared to individuals with lower CER [19]. Disinhibition is consistently and positively related to BW and BMI [20] and may increase an individual's susceptibility to food overconsumption in certain situations and/or emotional states that may result in weight gain over time. The significant relationship between grit and disinhibition suggests that non-cognitive traits may facilitate dispositions that foster control over BW regulation and that



disinhibition may serve as the behavioral proxy of grit. Grit can be easily measured through eight non-food related questions, thereby preventing questionnaire fatigue and avoiding food- and weight-related triggers that may arise from eating-related survey instruments. Because the usefulness of grit as a predictor of BW or BMI, compared to other eating behavior traits, is unclear, further evaluation of grit in BW management success over time is necessary. For example, individuals with higher grit and lower disinhibition may require less intervention and/or support to achieve BW goals, compared to individuals with lower grit and higher disinhibition who may require additional support, as suggested by Salles and colleagues [5], as well as for those that may be susceptible to barriers preventing goal achievement (in this case, successful weight gain prevention or management). If such a relationship exists, grit could be easily assessed during screening visits and interventions and/or treatment options could be tailored to improve adherence or outcomes.

The current cross-sectional study provides a snapshot of grit and eating behaviors in a small sample of women and cannot infer causation. No studies have examined the ability of an intervention to modify grit toward the goal of weight management or whether grit is correlated with weight management over time. Further, it is unknown whether grit is an antecedent to disinhibition in body mass regulation. Relationships explored here should be expanded to larger samples of men and women and tested in longitudinal studies. Instruments used in the current study can be easily administered in clinical and community settings.

Women with higher grit may have better control over BW and BMI as supported by lower disinhibition and hunger and higher CER, yet, disinhibition score but not Grit-S score predicted BW and BMI. Further research is warranted to determine the salience of grit in the field of weight management and to gain a better understanding of how grit relates to other eating behaviors in the context of long-term BW regulation.

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Table 6.1. Standardized (beta) and unstandardized (b-value) regression coefficients for predictors of body weight and body mass index in a sample of women before undergoing a weight gain prevention intervention

Variable	Beta	b-value	F-value	Adjusted R <sup>2</sup>
<b>Body weight</b>				
Model 1 (n=79)			4.458*	0.081
Grit-S score	-0.117	-3.428		
Disinhibition score	0.252*	1.516		
Model 2 (n=79)			8.022**	0.083
Disinhibition score	0.307**	1.850		
<b>Body mass index</b>				
Model 1 (n=79)			4.002*	0.071
Grit-S score	-0.121	-1.272		
Disinhibition score	0.232	0.503		
Model 2 (n=79)			7.054**	0.072
Disinhibition score	0.290**	0.627		

\*P≤0.05; \*\*P≤0.01. Backward elimination regression, including significantly related variables in Model 1 for BW (Grit-S score: r=−0.24, P<0.05, disinhibition score: r=0.31, P<0.01) and BMI (Grit-S score: r=−0.23, P<0.05, disinhibition score: r=0.29, P<0.01).

**ABSTRACT**

**OBJECTIVE:** This prospective study explored the association of grit, cognitive eating restraint (CER), disinhibition and hunger in predicting body weight (BW) and BW change over 12 months.

**METHODS:** The Short Grit Scale (Grit-S) and Eating Inventory (EI) were completed by 79 women [mean±SD, age: 31.5±8.2 y, BW: 76.3±19.2 kg, body mass index (BMI): 28.0±6.9 kg/m<sup>2</sup>] at baseline and after completion of a 1-year weight gain prevention intervention.

**RESULTS:** Average Grit-S, CER, disinhibition and hunger scores did not significantly change over time. Body weight and BMI, respectively, at baseline and month 12 were negatively associated with baseline grit (baseline:  $r=-0.24$ ,  $P<0.05$ ;  $r=-0.23$ ,  $P<0.05$ ; month 12:  $r=-0.25$ ,  $P<0.05$ ;  $r=-0.23$ ,  $P<0.05$ ) and positively associated with disinhibition (baseline:  $r=0.31$ ,  $P<0.01$ ;  $r=0.29$ ,  $P<0.01$ ; month 12:  $r=0.34$ ,  $P<0.01$ ;  $r=0.31$ ,  $P<0.01$ ). Change in BW was not associated with any measure. Lower baseline disinhibition and greater increase in CER over time were related to successful weight gain prevention (both  $P<0.05$ ). Disinhibition predicted month 12 BW ( $F=9.80$ ,  $P<0.01$ ) and BMI ( $F=8.08$ ,  $P<0.01$ ). No measures significantly predicted BW change.

**CONCLUSIONS:** Successful body weight regulation over 12 months was characterized by low disinhibition at baseline and an increase in CER over time. Additionally, high grit and low disinhibition at baseline were related to lower BW and BMI at end of study. Future interventions should consider strategies that manage disinhibition and increase CER.

**KEYWORDS:** Disinhibition; Grit; Obesity; Weight management; Weight regulation; Women

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<sup>6</sup>To be submitted to *Eating Behaviors*.

## 1. INTRODUCTION

Regulation and management of body weight (BW) over time remains a challenge for most individuals, namely women during young adulthood (Ball, Brown, & Crawford, 2002; Sheehan, DuBrava, DeChello, & Fang, 2003). Weight management is made difficult by the complex interplay among lifestyle, environmental and genetic factors (Mitchell, Catenacci, Wyatt, & Hill, 2011). Additionally, personality traits may play a role in weight management (Sutin, Ferrucci, Zonderman, & Terracciano, 2011) and have been shown to be significant predictors of BW (Chapman, Fiscella, Duberstein, Kawachi, & Coletta, 2009; Terracciano, Sutin, McCrae, Deiana, Ferrucci, Schlessinger, Uda, & Costa, 2009). More attention to certain personality traits may help to tailor weight management approaches.

Grit is one such non-cognitive personality trait that may play a role in BW regulation. Defined as the “perseverance and passion for long-term goals” (Duckworth, Peterson, Matthews, & Kelly, 2007, p. 1087), grit encompasses the sustained interest and efforts of individuals to achieve long-term objectives even in presence of failures, plateaus or diversity. Previous research has shown grit to be a predictor of success in academic pursuits (Duckworth et al., 2007; Duckworth & Quinn, 2009; Eskreis-Winkler, Shulman, Beal, & Duckworth, 2014), workplace settings (Duckworth, Quinn, & Seligman, 2009; Eskreis-Winkler et al., 2014), military retention (Duckworth et al., 2007; Eskreis-Winkler et al., 2014) and relationships (Eskreis-Winkler et al., 2014). In the medical field, low grit may be a risk factor for not completing residency (Burkhart, Tholey, Guinto, Yeo, & Chojnacki, 2014) and has been predictive of lower levels of general psychological health among surgical residents (Salles, Cohen, & Mueller, 2014).

The cognitive personality traits of cognitive eating restraint (CER), disinhibition and hunger are known to influence BW management (Stunkard & Messick, 1985; Lowe & Maycock, 1988; Dykes, Brunner, Martikainen, & Wardle, 2003; Beiseigel & Nickols-Richardson, 2004; Nickols-Richardson, Coleman, Volpe, & Hosig, 2005; Hays & Roberts, 2008; Urbanek, Metzgar, Hsiao, Piehowski, & Nickols-Richardson, 2015). Cognitive eating restraint is the conscious restriction of dietary intake with the motive to control BW or induce weight loss (Stunkard et al., 1985; Hays et al., 2008), while disinhibition is characterized by the tendency to consume

excess amounts of foods in response to a variety of stimuli (Lowe et al., 1988; Hays et al., 2008). Hunger is defined as the susceptibility to consume foods in response to physiological signs and symptoms that signal the need for nourishment (Lowe et al., 1988). Disinhibition is consistently positively associated with anthropometric measurements (Bryant, King, & Blundell, 2007; French, Epstein, Jeffery, Blundell, & Wardle, 2012), while the relationships between CER and hunger and anthropometric measurements are not as clear (Drapeau, Provencher, Lemieux, Després, Bouchard, & Temblay, 2003). The interaction of these cognitive personality traits may predict current BW and BW regulation over time, and when considered in combination with non-cognitive personality traits such as grit, may provide further insight about the predictors of BW and BMI over time.

The current prospective study aimed to explore the association and role of grit, CER, disinhibition and hunger in predicting BW status and BW change over 12 months in a sample of healthy premenopausal women enrolled in a randomized controlled trial of weight gain prevention. It was hypothesized that baseline grit, disinhibition and hunger scores would be negatively associated and CER would be positively associated with BW and BMI at month 12. Grit also was hypothesized to be a significant predictor of body weight change over time.

## **2. METHODS**

### **2.1 Participants**

Healthy premenopausal women between the ages of 18 and 45 years with a BMI of  $>18.5\text{kg/m}^2$  were recruited from the East Central Illinois (USA) communities of Champaign-Urbana. Women who met age (18-45 years) and BMI ( $>18.5\text{kg/m}^2$ ) criteria and had a desire to prevent weight gain were further screened for eligibility. Women who self-reported metabolic, cardiovascular or musculoskeletal abnormalities, used medications to manage chronic conditions or self-reported use of supplements or medications known to influence BW regulation were excluded. Additional exclusion criteria included a score of  $>50$  on the Zung Self-Rating Depression Scale/Status Inventory (Zung, 1965), indicating the presence of depressive symptomology; amenorrhea ( $\leq 8$  menstrual cycles/y); or history of weight loss surgery. Women who were pregnant or planned to become pregnant, or who were currently lactating also were

excluded. Full details of this 1-year randomized controlled trial of weight gain prevention have been previously described (Metzgar & Nickols-Richardson, 2015).

The study protocol (#14397) was approved by the Institutional Review Board (IRB) for the Protection of Human Subjects at the University of Illinois at Urbana-Champaign. Prior to study participation, all participants provided written informed consent.

## **2.2 Measurements**

Participants completed self-administered paper-based questionnaires upon enrollment (baseline) and at the end of the 1-year intervention (month 12). Body weight and BMI also were collected and evaluated at baseline and month 12.

### *2.2.1 Grit*

Grit was assessed at baseline and month 12 using the Short Grit Scale or Grit-S (Duckworth & Quinn, 2009). This 8-item questionnaire utilizes a 5-point Likert scale where 1 = strongly disagree and 5 = strongly agree. Women rated how well statements such as “I have difficulty maintaining my focus on projects that take more than a few months to complete” and “Setbacks don’t discourage me” described their tendencies (Duckworth & Quinn, 2009). Grit-S score was calculated by averaging the eight items with possible scores ranging from 1-5. A high Grit-S score is indicative of greater grit. Internal consistency reliability ranges from 0.73 to 0.84 in previous studies (Duckworth & Quinn, 2009; Von Culin, Tsukayama, & Duckworth, 2014; Eskreis-Winkler et al., 2014).

### *2.2.2 Eating constructs*

Cognitive eating restraint, disinhibition and hunger were measured at baseline and month 12 using the Eating Inventory (EI) (Stunkard et al., 1985). This 51-item questionnaire is comprised of 36 true/false statements (Part 1) and 15 4- or 6-point Likert scale questions (Part 2), with 21 items that assess CER, 16 items that assess disinhibition and 14 items that address hunger. Standard scoring methods were used to calculate subscale scores for each construct (Stunkard et al., 1985), with higher scores indicating greater tendencies related to the corresponding construct.

### *2.2.3 Body weight and body mass index*



Body weight and standing height were measured at baseline and month 12; these measurements were used to calculate BMI ( $\text{kg}/\text{m}^2$ ). A calibrated scale (Tanita 410GS, Arlington Heights, IL, USA) and stadiometer (Seca 700, Hanover, MD, USA) were used to measure BW and standing height, respectively; these measures were recorded to the nearest 0.1 kg and 0.1 cm, respectively.

#### *2.2.4 Body weight change and weight gain prevention*

Percent BW change was calculated by subtracting baseline BW from month 12 BW and dividing by baseline BW. Currently, there is no standardized definition of weight gain prevention; thus, weight gain prevention, or weight maintenance, was defined in the current study as a BW change of  $\pm 3\%$  from baseline to month 12 (Stevens, Truesdale, McClain, & Cai, 2006). A weight loss of  $>3\%$  of baseline BW or a weight gain of  $>3\%$  of baseline BW was considered unsuccessful weight gain prevention.

### **2.3 Statistical Analyses**

All women who provided complete Grit-S and EI ( $n=79$ ) questionnaires at baseline were included in intention to-treat analysis. Participant characteristics were analyzed by descriptive statistics (means $\pm$ SD). Paired *t*-tests were used to evaluate changes in grit, EI constructs, BW and BMI. Independent *t*-tests were used to compare differences between women who met weight gain prevention criteria with those who did not. The relationship between baseline Grit-S score and month 12 BW, BMI and percent BW change were examined using Pearson's correlation coefficients. To assess usefulness of grit as a predictor of percent BW change, backward elimination regression was used. All statistical analyses were conducting using the Statistical Package for the Social Sciences (version 22.0, 2013, IBM Corp, Armonk, NY, USA) with significance set at  $P<0.05$ .

### **3. RESULTS**

Eighty-one participants enrolled in the study with 79 of these women providing complete Grit-S and EI data. A majority of women (age:  $31.5\pm 8.2$  y) were non-Hispanic white ( $n=53$ , 67%), had earned at least a college degree ( $n=60$ , 76%) and had a total annual household

income of  $\geq$ \$50,000 (n=43, 54%). On average, women were overweight (BMI:  $28.0\pm 6.9$  kg/m<sup>2</sup>), and BW ranged from 47.4 to 139.2 kg (mean:  $76.3\pm 19.2$  kg). Body weight and BMI did not significantly change over the 1-year study interval. Percent BW change was  $0.8\pm 4.3\%$ , with 48 women (60.8%) meeting weight gain prevention criteria.

Average Grit-S scores (ranges) at baseline and month 12 were  $3.4\pm 0.7$  (2.0-4.6) and  $3.5\pm 0.7$  (1.5-4.8). Baseline and month 12 Grit-S scores were not significantly different. At baseline, the average score (range) was  $9.1\pm 3.5$  (2-17) for CER,  $7.6\pm 3.2$  (1-14) for disinhibition and  $5.6\pm 2.8$  (0-13) for hunger. These scores did not change significantly over time with average scores of  $9.4\pm 3.4$  (2-18),  $7.3\pm 3.4$  (1-16) and  $5.4\pm 3.1$  (0-13) for CER, disinhibition and hunger, respectively, at month 12. Women who met weight gain prevention criteria had significantly lower baseline disinhibition scores ( $P<0.05$ ) and significantly increased CER over the intervention ( $P<0.05$ ) as compared to women who did not prevent weight gain.

Baseline Grit-S was negatively associated with BW and BMI at baseline ( $r=-0.24$ ,  $P<0.05$ ;  $r=-0.23$ ,  $P<0.05$ ) and month 12 ( $r=-0.25$ ,  $P<0.05$ ;  $r=-0.23$ ,  $P<0.05$ ). Baseline disinhibition was positively associated with BW and BMI at baseline ( $r=0.31$ ,  $P<0.01$ ;  $r=0.29$ ,  $P<0.01$ ) and month 12 ( $r=0.34$ ,  $P<0.01$ ;  $r=0.31$ ,  $P<0.01$ ). Neither CER nor hunger were significantly associated with BW and BMI at either baseline or month 12. Baseline Grit-S, CER, disinhibition and hunger were not associated with percent BW change.

Together, baseline CER, hunger, disinhibition and Grit-S scores explained approximately 8% of the variability in month 12 BW. Approximately 9% of the variability in month 12 BW and 8% of the variability in month 12 BMI was explained by baseline hunger, disinhibition and Grit-S scores. Together, disinhibition and Grit-S scores at baseline explained 10% of the variability in month 12 BW and 8% of the variability in month 12 BMI. Disinhibition alone explained approximately 10% of the variability in month 12 BW and 8% of the variability in month 12 BMI. Of the variability included in the current analyses, baseline disinhibition score was the only significant predictor of BW and BMI at the end of this 1-year intervention (Table 7.1). No variables were significant predictors of percent BW change.

#### 4. DISCUSSION

The purpose of this study was to examine the role of grit and eating behaviors in predicting BW, BMI and BW change in a sample of premenopausal women enrolled in a 12-month randomized controlled trial of weight gain prevention (Metzgar et al., 2015). The hypotheses established *a priori* were partially supported. Baseline grit and disinhibition were negatively associated with BW and BMI at month 12; no associations for CER, hunger or BW change were observed. Further, grit was not found to be a significant predictor of BW change over a 12-month intervention period. To our knowledge, this is the first study to examine grit as a predictor of BW change over time and only one other study has cross-sectionally explored the association of grit with BW and BMI (Metzgar & Nickols-Richardson, under review).

In this sample of healthy premenopausal women, grit at baseline and month 12 were highly correlated, and grit did not change over time. These results are consistent with others that have shown grit to be relatively stable over time (Duckworth et al., 2007; Duckworth & Quinn, 2009; Von Culin et al., 2014; Salles et al., 2014). Further, Grit-S scores in the current study are comparable with those reported in previous studies (Duckworth et al., 2007; Von Culin et al., 2014; Salles et al., 2014), indicating that the women enrolled in the present study are representative of women with similar characteristics.

Eating behavior scores at baseline also were highly correlated with scores at month 12. Women who successfully prevented weight gain over the 12-month intervention period were characterized by lower disinhibition levels at baseline and increases in CER over time. These findings are consistent with a previous weight gain prevention study of adult women (Levine, Klem, Kalarchian, Wing, Weissfeld, Qin, & Marcus, 2007) in which women who met weight gain prevention criteria (>2 pound BW loss or  $\pm 2$  pounds of baseline weight) significantly increased CER and significantly decreased disinhibition over a 3-year study period. An additional study of weight gain prevention in young adults (Wing, Tate, Espeland, Gorin, LaRose, Robichaud, Erickson, Perdue, Bahson, & Lewis, 2013) also collected eating behaviors data, but results are not yet available.

Although the non-cognitive personality trait of grit did not predict success in BW management in this sample of women enrolled in weight gain prevention study, these findings

may be different in a study designed to induce BW loss. Grit has been identified as a marker of success or commitment in a variety of settings, even during challenges and failures (Duckworth et al., 2007; Duckworth & Quinn, 2009; Duckworth, Quinn, & Seligman, 2009; Eskreis-Winkler et al., 2014; Salles et al., 20014; Burkhart et al., 2014). The current weight gain prevention trial did not employ a dietary intervention or energy restriction so there was no marker of compliance; individuals with higher grit may be more likely to comply with an energy restricted diet and achieve weight loss.

While baseline levels of grit, CER, disinhibition and hunger did not predict percent BW change, they did predict absolute BW and BMI at 12 months. The finding of disinhibition as the strongest predictor of 12 month BW and BMI was to be expected as there is a consistent positive relationship between disinhibition, BW and BMI (Bryant et al., 2007; French et al., 2012). The identification of the stimuli or emotional states that lead to the susceptibility to overconsume foods may be useful in identify periods that may accompany weight gain and tailor interventions to individuals in order to better facilitate weight gain prevention. The relationships between CER and BW and BMI are not as consistent, but increasing levels of CER may be helpful in preventing weight gain over time or inducing BW loss (Levine et al., 2007; Savage, Hoffman, & Birch, 2009; Nickols-Richardson et al., 2005). Interventions that include self-regulation and other educational strategies that address CER may be useful in preventing weight gain over time.

Even though the non-cognitive personality trait of grit is relatively stable over time (Duckworth et al., 2007; Duckworth & Quinn, 2009; Von Culin et al., 2014; Salles et al., 2014), grit has been suggested to increase over the lifespan (Duckworth et al., 2007) and differ by individual domain (i.e., careers vs. hobbies vs. relationships) (Duckworth & Quinn, 2009). No studies have examined the role of an intervention to modify grit, but it has been suggested that targeted interventions may improve grit (Duckworth et al., 2007; Duckworth 2009).

Grit and disinhibition levels were significantly and negatively associated at both baseline and month 12 which supports that grit may serve as the non-cognitive proxy for disinhibition (Metzgar et al., under review). The Grit-S is shorter and more easily administered when compared to the EI which may be lengthy for some individuals and trigger emotions related to

statements that address feelings and perceptions related to food intake. In more intensive interventions or programs, grit may also be useful in identifying individuals who may require additional support (Burkhart et al., 2014; Salles et al., 2014). Although grit was not related to participant drop out in the current study, grit has been identified as a possible marker for attrition in surgical residents (Burkhart et al., 2014) and this relationship should be examined in more intensive or “strict” weight loss interventions or programs.

The relationships explored in the current study should be examined in similar samples of women and repeated in men. Additionally, more research is needed regarding the role of grit in weight management. The current study only assessed weight gain prevention; the role of grit in weight loss and weight loss maintenance offer opportunities for future research.

Weight regulation over time is a challenging task and a better understanding of the interaction between cognitive and non-cognitive personality trait is necessary. High levels of grit and low levels of disinhibition translated to lower BW and BMI at the end of a 12-month intervention in a sample of premenopausal women. Additionally, women with low disinhibition and those who were able to increase CER over 12 months were more successful in preventing weight gain over time. In order to facilitate weight gain prevention, attention should be given to managing disinhibition and increasing CER over time.

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Table 7.1. Standardized (beta) and unstandardized (b-value) regression coefficients for predictors of body weight and body mass index at the conclusion of a 1-year randomized controlled trial of weight gain prevention in a sample of premenopausal women

Variable	Beta	b-value	F-value	Adjusted R <sup>2</sup>
<b>Body weight (month 12)</b>				
Model 1 (n=79)			2.696*	0.080
Baseline restraint score	0.014	0.076		
Baseline hunger score	-0.057	-0.392		
Baseline Grit-S score	-0.126	-3.731		
Baseline disinhibition score	0.293*	1.782		
Model 2 (n=79)			3.638*	0.092
Baseline hunger score	-0.058	-0.397		
Baseline Grit-S score	-0.123	-3.642		
Baseline disinhibition score	0.293*	1.783		
Model 3 (n=79)			5.374**	0.101
Baseline Grit-S score	-0.119	-3.510		
Baseline disinhibition score	0.280*	1.701		
Model 4 (n=79)			9.803**	0.101
Baseline disinhibition score	0.336**	2.043		
<b>Body mass index (month 12)</b>				
Model 1 (n=79)			3.137*	0.076
Baseline hunger score	-0.090	-0.223		
Baseline Grit-S score	-0.115	-1.237		
Baseline disinhibition score	0.278*	0.614		
Model 2 (n=79)			4.414*	0.080
Baseline Grit-S score	-0.108	-1.163		
Baseline disinhibition score	0.257*	0.568		
Model 3 (n=79)			8.081**	0.083
Baseline disinhibition score	0.308**	0.681		

\*P≤0.05; \*\*P≤0.01. Backward elimination regression including significantly related variables.

## CHAPTER 8: Conclusions and future directions

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The current 1-year randomized controlled trial was successful in preventing weight gain in a sample of healthy normal weight, overweight and obese premenopausal women between the ages of 18 and 45 years, but there were no differences between women who received nutrition education and those who were randomized to a control group (CON). Further, there were no significant differences in weight gain prevention between women randomized to receive the weight gain prevention intervention from a dietitian (RDG) compared to those who received the same weight gain prevention intervention from a counselor (CSG). Taken together, these findings demonstrate that weight gain prevention is possible; however, nearly 40% of the sample population still struggled with weight gain prevention. Further evaluation of determinants of prospective weight gain and strategies for preventing weight gain is necessary to effectively reduce the burden of adult obesity.

Although no clinically significant differences were observed between the RDG, CSG and CON over time for any primary or secondary outcome measures, the collection and evaluation of clinical markers beyond body weight is a major strength of this study. Health is multidimensional, and using body weight as the “gold standard” for health may actually be more harmful, as body weight is only one component of the multidimensional health puzzle. Other indicators of health, including hip and waist circumference, body composition, blood pressure and blood lipid levels, in combination with body weight may provide greater insight into metabolic health of an individual.

In addition to clinical outcomes, health perceptions, behaviors and psychosocial outcomes should also be considered as behavior and lifestyle choices directly impact body weight and other health outcomes. Grit, along with other personality traits, should be evaluated as these may play a role in body weight regulation. Behavior and lifestyle changes, in the form of a weight gain prevention/health promotion approach, may play a larger role in improving long-term health and weight status as compared to a weight loss treatment approach. The current weight gain prevention trial was designed to remove the emphasis from energy restriction in order to encourage “big picture” healthy dietary, physical activity and

lifestyle behaviors (i.e., sleep, stress management) in order to promote health and weight maintenance.

Energy restriction and other methods to induce weight loss are successful in the short term (1,2), but these methods have failed to produce sustained weight loss and significantly impact rates of overweight and obesity (3,4). Beyond lack of success related to weight loss and weight loss maintenance, unintended consequences such as metabolic abnormalities due to weight cycling, increased preoccupation with foods and decreased self-esteem may result from an emphasis on weight loss (3). Weight gain prevention and health promotion approaches that serve as an alternative to treatment via weight loss are warranted, but little is known regarding the determinants of weight gain prevention due to a limited body of evidence with discouraging findings.

The Health at Every Size (HAES) movement is gaining momentum (5), as is the notion that individuals may be overweight or obese and metabolically healthy or normal weight and metabolically unhealthy (6,7). The HAES approach to weight management focuses on health promotion by improving metabolic fitness and decreasing chronic disease risk by increasing physical activity and consumption of nutrient dense foods (3,5). Treatment approaches, including dose and intensity, may differ between metabolically healthy and unhealthy individuals (7).

Future research should focus on identifying strategies to improve overall health and well-being while minimizing weight gain that accompanies young adulthood and continues through midlife. While the current trial included only premenopausal women, weight gain prevention should be addressed across the lifespan for both genders. Specifically, strategies for and determinants of weight gain prevention may differ between different age segments of the population. The perceived risk of weight gain for the college population may be much different than that of post-partum woman. Further, men and post-menopausal women are underrepresented in much of the weight management literature, and more attention should be given to these populations. A one-size-fits-all approach is not appropriate to significantly impact health by preventing weight gain.

Another consideration for future weight gain prevention interventions is the inclusion of couples. Research has shown that spousal body weights are correlated and that when one spouse's body weight increases, so does that of the other spouse; the likelihood of developing obesity increases as well (8). Even though outcome expectations, self-efficacy or perceived susceptibility may differ between partners, similar behaviors are still likely shared. Additionally, spouses may serve as an external source of support and accountability, both of which have been identified as key facilitators to weight loss and weight loss maintenance (9).

As most weight gain prevention studies have fallen short of the objective to prevent weight gain, further consideration should be given to intervention design. The FITT (frequency, intensity, time and type) principle, is used in the development of exercise prescriptions (10); these components can also be applied to developing successful weight gain prevention interventions. Frequency would relate to how often the intervention component occurs (i.e., daily, weekly, monthly, yearly); intensity (i.e., the level of personal commitment); time (i.e., the length of the intervention, including follow up); and type (i.e., newsletters, web or technology based, individual counseling, group sessions). Using the FITT principle also allows for tailored programs or interventions.

Finally, an agreement as to what constitutes successful weight gain prevention is needed. Multiple definitions have been used inconsistently throughout the literature which makes comparisons difficult in the already limited body of evidence. A standardized definition of weight gain prevention would allow comparisons across studies to determine the true prevalence of successful weight gain prevention. Further, identifying individuals who are successful at weight gain prevention would allow researchers to gain insight into habits, characteristics or strategies used by these individuals, similar to the concept of the National Weight Control Registry (11).

In summary, more interventions, that include long-term follow ups with continued contact and that target strategies for and determinants of weight gain prevention are warranted. Further, larger sample sizes are necessary, as are studies that target different segments of the lifespan. Additionally, future interventions should include more robust indicators of health such as blood pressure, blood lipid levels, dietary and physical activity

behaviors and related psychosocial outcomes such as self-efficacy, social support and self-regulation and move away from body weight as the best (or only) indicator of health.

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## APPENDIX A: IRB approval letter

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### UNIVERSITY OF ILLINOIS AT URBANA - CHAMPAIGN

Office of the Vice Chancellor for Research  
Institutional Review Board  
528 East Green Street  
Suite 203  
Champaign, IL 61820



March 7, 2014

Sharon Nickols-Richardson  
Food Science & Human Nutrition  
260A Bevier Hall  
905 S. Goodwin Ave  
M/C 182

RE: *Determinants of weight gain prevention in adult women*  
IRB Protocol Number: 14397

Dear Dr. Nickols-Richardson:

Your response to stipulations for the project entitled *Determinants of weight gain prevention in adult women* has satisfactorily addressed the concerns of the UIUC Institutional Review Board (IRB) and you are now free to proceed with the human subjects protocol. The UIUC IRB approved, by expedited review, the protocol as described in your IRB-1 application with stipulated changes. The expiration date for this protocol, UIUC number 14397, is 03/05/2015. The risk designation applied to your project is *no more than minimal risk*. Certification of approval is available upon request.

Copies of the attached date-stamped consent form(s) must be used in obtaining informed consent. If there is a need to revise or alter the consent form(s), please submit the revised form(s) for IRB review, approval, and date-stamping prior to use.

Under applicable regulations, no changes to procedures involving human subjects may be made without prior IRB review and approval. The regulations also require that you promptly notify the IRB of any problems involving human subjects, including unanticipated side effects, adverse reactions, and any injuries or complications that arise during the project.

If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact me or the IRB Office, or visit our Web site at <http://www.irb.illinois.edu>.

Sincerely,



Anita Balgopal, PhD  
Director, Institutional Review Board

Attachment(s)

c: Catherine Metzgar

UNIVERSITY OF ILLINOIS  
AT URBANA-CHAMPAIGN



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Dr. Shelly Nickols-Richardson, Professor and Head  
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**Informed Consent Form**

The University of Illinois, Urbana-Champaign

**Title of Project:** Determinants of Weight Gain Prevention in Adult Women

**Principal Investigator:**

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**1. Purpose of the study:** The purpose of this research is to identify factors that will help to prevent weight gain in women who are between the ages of 18 to 45 years. This study will look at the ability of nutrition education to prevent weight gain and to see which things related to this education are the most helpful in weight gain prevention. A total of 180 premenopausal women who are normal weight, overweight or obese (have a body mass index of greater than 18.5 kg/m<sup>2</sup>) will be in this study. Individuals who have a body mass index of less than 18.5 kg/m<sup>2</sup> are considered underweight and are not eligible for the study. Body mass index is a measure of your weight in relation to your height and is used as an indicator of weight status. The Agricultural Experiment Station at the University of Illinois is funding this study.

**2. Procedures to be followed:** As a participant, you will be asked to complete screening forms. If enrolled in the study, you will attend 2 informational meetings, 5 blood collection sessions (testing sessions), and weekly nutrition education sessions for 4 months and monthly nutrition education sessions for 8 months during this 12-month study. During the study, you will complete several procedures:

Informational Meeting – 1 hour of your time.

You will attend an initial informational meeting where the details of the study will be explained. You will have plenty of time to ask questions of the investigators and will have up to 2 weeks after the meeting to decide not to be in the study. No further measurements will be taken until we receive your final agreement or consent to be in the study.

At the informational meeting, you will:

- review your signed Informed Consent Form and reaffirm or agree again your desire and willingness to be in the study (within 2 weeks of the meeting);
- ask questions about the study; and

*telephone 217-244-4498 • fax 217-333-9689*



- be instructed on how to use an accelerometer (a tool that measures your activity) and how to properly fill out a 4-day food record and 7-day physical activity record.

After the informational meeting and your agreement to be in the study, you will undergo baseline testing. After this testing, you will be randomized into a nutrition education group. This means that you will be put into 1 of 3 groups by chance. Once you are assigned to a group, you will attend another meeting specifically for your assignment. At this meeting that will take 1 hour of your time, we will discuss the study, answer any of your questions, and give you a schedule for your testing sessions, weekly nutrition education meetings, and the date on which the study will start. You will stop using or taking any vitamin and mineral supplements until the end of the study.

#### Nutrition Education Groups

The 3 groups include: 1) 1 nutrition education group; 2) 1 nutrition education group; and 3) 1 wait-list control group. If you are in 1 of the nutrition education groups, you will meet weekly for the first 16 weeks, and then once each month for the remaining 8 months. Each of these meeting will last for 1 hour. If you are in the wait-list control group, you will attend only the testing sessions for the first 12 months of the study, and then you will be assigned to 1 of the nutrition education groups at a later date.

#### Testing Sessions

At baseline (before the nutrition education begins), and after 3, 6, 9, and 12 months of the study, you will complete a testing session. This will take about 2 hours of your time at each testing session. During each testing session, you will need to:

- arrive in Bevier Hall on the campus of the University of Illinois, Urbana-Champaign at your scheduled appointment day and time after having not had anything to eat from 11:00 pm until after the testing session is over;
- turn in a 4-day food record, accelerometer counts, and a 7-day physical activity record;
- have your height, weight, body fat percentage, waist circumference, and hip circumference measured;
- complete a General Demographic Form; Current Illness questionnaire; a General Symptoms questionnaire; and the SF-36 Health Status questionnaire;
- complete the Zung Scale; Eating Inventory; Grit-S Questionnaire; and SCT Questionnaire;
- have your blood pressure and resting heart rate measured;
- have about 30 mL (about 2 Tablespoons) of whole blood drawn from your arm by a trained professional who is trained in drawing blood from people; and
- eat breakfast foods and beverages if desired.

Weekly Nutrition Education Sessions – 1 hour of your time each week for the first 16 weeks of the study and then 1 hour of your time each month for the last 8 months of the study.

At these sessions, we will discuss general nutrition information, food purchasing and preparation, eating in restaurants and in social settings, recipe modifications, physical activity, fruits and vegetables, portion control, breakfast consumption, healthy snacking, family menu planning, and grocery shopping, among other nutrition topics. A professional will lead your nutrition education session. Other women in the study will attend your sessions.

#### Follow-up Meeting

Once everyone has finished the whole study, we will have 1 last meeting. At this meeting, you will be given your study results, and we will provide information about the study.

### Clothing during Testing Sessions

You should wear a short-sleeved or loose-fitting shirt for the blood draw and elastic-waisted pants for the waist and hip circumference measurements. Do not wear expensive jewelry or many clothing accessories to the test sessions, as you will have to remove these items during measurement of weight.

### Length of Time for Study Procedures

Your appointments may take more or less time than estimated to complete each procedure. You will be given plenty of time to complete measurements and blood draws and to understand your nutrition education information.

**3. Discomforts and risks:** There are 3 potential risks: 1) blood draws, 2) still photos and 3) exposure of personal information. There is minimal risk involved in blood draws. A bruise or a little bleeding may result from blood collection procedures with no known harmful effects to your health or well-being. In order to minimize bruising and bleeding, a trained individual will draw all blood samples. You may become slightly lightheaded or nauseous during blood draws, but you may sit or recline for as long as you need to minimize discomfort. After each blood draw, you will be provided with breakfast foods and beverages. Two attempts to draw blood (or 2 needle sticks) will be allowed. If a second attempt is unsuccessful, no further tries for blood collection will be done. Research personnel will take universal blood precautions during handling of all blood samples.

During the study, still photographs will be taken of participants. Photographs will be taken during nutrition education sessions and during testing sessions. Your image as captured in a photograph may be used during presentations and in publications put together by the investigators of the study. Your name will not be attached to your picture. Any information that you give to the investigators will not be individually attached to your picture. It is possible that someone will recognize your image or your picture. Therefore, your participation in the study will not be anonymous and the confidentiality of your being in this study may not be guaranteed. There is minimal risk involved with a still photo; however, your image as part of this study may pose a discomfort to you. If you do not want to have your picture or still photo taken during the study, please inform the investigators.

Please check one of the boxes below.

I consent to have my photograph taken throughout the course of the study:  Yes  No

Exposure of personal information may occur during data collection and education sessions, and you may experience slight embarrassment and/or discomfort. You may skip any questions you do not wish to answer and your data collection sessions will be completed in private. During group education sessions, investigators will keep all information private, but it cannot be guaranteed that other participants will do the same.

**4. Abnormal test results:** Your blood pressure result will be shared with you at each testing session. If your systolic (top number) blood pressure measurement is 140 mmHg or more and/or if your diastolic (bottom number) blood pressure measurement is 90 mmHg or more, you will be told to seek immediate medical attention from your health care provider, and the investigator will remove you from the study.

The blood samples will not be analyzed until the study has been completed. However, after all participants have completed their blood draws, we will have a follow-up meeting. At this meeting, you will be given your personal results. If there are any study results that suggest that medical attention is needed (for example, high blood cholesterol), you will be made aware of this within 30 days of analysis and recommended to contact your health care provider for an examination. Dietary and physical activity records will also be analyzed at the end of the study, and information will be shared with you at this time.

This study is being done for research purposes and not for medical reasons. If you have a test result that is outside of the normal range, you will be informed and told to seek medical care from your health care provider.

The blood samples that you provide during this study will become property of the University of Illinois, Urbana-Champaign. Samples will be stored as needed to complete the study.

**5. Benefits to individual:** You may benefit from participation in this study in several ways including: 1) nutrition education; 2) analysis of blood cholesterol and blood sugar levels; 3) blood pressure measurements; and 4) dietary intake analysis. You may or may not prevent weight gain, but you will receive nutrition education. You will be provided with your results from tests after the study has been completed. Referral to appropriate health care professionals will be provided, if necessary based on your results after the completion of the study.

**6. Benefits to society:** This research will benefit society by finding what nutrition-related information helps women prevent weight gain.

**7. Duration/time of the procedures and study:** The study will have 2 informational meetings, 5 testing sessions, weekly nutrition education sessions for 4 months and then monthly nutrition education sessions for 8 months, and a follow-up meeting. The informational meetings will last approximately 1 hour, 5 testing sessions will last approximately 2 hours each, the weekly and then monthly nutrition education sessions will last 1 hour each, and the follow-up meeting will last about 1 hour. The total time for this study is estimated at 37 to 40 hours over a 12-month period. You may also spend time during each day thinking about, preparing and eating food and recording food intake and physical activity.

Absences and vacations will be expected and accommodated with attention given to scheduling of your data collection sessions and educational sessions. Make-up sessions will be offered if you are unable to attend an educational session, and educational materials will be mailed if necessary.

**8. Statement of confidentiality:** Your participation in this study is confidential. Data that you provide to the investigators will be stored and secured in the investigators' offices in locked filing cabinets. A 3-digit code or identification number will be assigned to you and used in place of your name. A master list of participants' code numbers will be kept in a separate locked filing cabinet. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. Only the investigators of this study or students of the Primary Investigator will be allowed access to any data. It is up to you to share your individual results with your primary health care provider, if you so choose.

Your picture or still photo may be used in presentations and publications related to this study. Your name will not be attached to your photograph, and your data will not be able to be identified to your photograph.

The following may review records related to this research: the University of Illinois' Office for Human Research Protections, the University of Illinois' Institutional Review Board, and the Office of Human Research Protections in the U.S. Department of Health and Human Services.

**9. Right to ask questions:** Please contact Dr. Shelly Nickols-Richardson (Primary Investigator) at [nickrich@illinois.edu](mailto:nickrich@illinois.edu) with questions, complaints or concerns about the research. You can also contact the investigator if you feel that this study has harmed you. If you have any questions, concerns, problems about your rights as a research participant or would like to offer input, please contact the University of Illinois' Office for Human Research Protections at 217-333-2670 or e-mail [irb@illinois.edu](mailto:irb@illinois.edu). The Office for Human Research Protections cannot answer questions about research procedures. All questions about research procedures can only be answered by the research personnel.

**10. Payment for participation:** You will receive a \$10 gift card for completing each of the testing sessions of the study. If you participate in all of the testing sessions, you will receive a total of \$50 in gift cards for the whole study. Total payments within one calendar year that exceed \$600 will require the University to report these payments to the IRS annually. This may require you to claim the compensation that you receive for being in this study as taxable income.

**11. Voluntary participation:** Your decision to be in this research is voluntary. You can stop at any time. You do not have to answer any questions you do not want to answer. Refusal to take part in or withdrawing from this study will involve no penalty or loss of benefits you would otherwise receive. There may be reasons for which the investigators find that you should discontinue the study, and they can remove you from the study at any time.

**12. Event of injury:** The University of Illinois does not provide medical or hospitalization insurance coverage for participants in this research study nor will the University of Illinois provide compensation for any injury sustained as a result of participation in this research study, except as required by law.

You must be between the ages of 18 to 45 years to be in this research study. If you agree to take part in this research study and with the information outlined above, please sign your name and indicate the date below.

You will be given a copy of this signed and dated consent form for your records.

UNIVERSITY OF ILLINOIS  
APPROVED CONSENT  
VALID UNTIL

MAR 05 2015

\_\_\_\_\_  
Participant Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

\_\_\_\_\_  
Date

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## APPENDIX B: Permission to reprint

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**From:** Carmen <jmir.editorial.office@gmail.com>  
**Sent:** Tuesday, May 12, 2015 5:01 AM  
**To:** Metzgar, Catherine J  
**Cc:** jmir.editorial.assistant@gmail.com  
**Subject:** Re: Permission to reprint

Please see the copyright at the bottom of your article and include that statement. You do not need our permission as it is your work and under a CC-BY license.

Regards,  
Carmen

Sent from my iPhone

On 12 May, 2015, at 01:39, Metzgar, Catherine J <[metzgar2@illinois.edu](mailto:metzgar2@illinois.edu)> wrote:

Hi Allison,

As I am putting my dissertation together, I would like to request permission to reprint the following paper of research that I conducted as a graduate student. Can you please advise on how to obtain permission to reprint?

Metzgar CJ, Nickols-Richardson SM. Determinants of weight gain prevention in young adult and midlife women: study design and protocol of a randomized controlled trial. *JMIR Res Protoc*. 2015;4(1):e36. doi: 10.2196/resprot.4008.

<http://www.ncbi.nlm.nih.gov/pubmed/25831450>

Thanks for your help.

Catherine Metzgar, RD  
Doctoral Candidate  
University of Illinois at Urbana-Champaign

**From:** 김정원 <kimjwe@snue.ac.kr>  
**Sent:** Tuesday, June 09, 2015 2:08 AM  
**To:** Metzgar, Catherine J  
**Subject:** Re:FW: RE: RE: Permission to reprint

Dear Ms. Catherine Metzgar,

For your request on the citation of your article published in NRP in your dissertation, the editorial board of NRP agreed to let you inform that you can make a statement as below:

This article previously appeared in its entirety as Sharon M. Nickols-Richardson, Kathryn E. Piehowski, Catherine J. Metzgar, Debra L. Miller and Amy G. Preston. Changes in body weight, blood pressure and selected metabolic biomarkers with an energy-restricted diet including twice daily sweet snacks and once daily sugar-free beverage. *Nutr Res Pract.* 2014;8(6):695-704; doi:10.4162/nrp.2014.8.6.695.[Epub ahead of print]. This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0/>) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

We feel sorry for the delay and any inconvenience while communicating with us, and hope you have continuous interests in publishing in NRP.

Thank you.

Sincerely,

Jeong-Weon Kim, Ph.D  
Editor of NRP

----- 원본 메일 내용 -----

보낸 사람 : "NutritionRP" <[nutritionrp@daum.net](mailto:nutritionrp@daum.net)>

받는 사람 : "김정원" <[kimjwe@snue.ac.kr](mailto:kimjwe@snue.ac.kr)>

메일 제목 : FW: RE: RE: Permission to reprint

보낸 날짜 : Tue, 09 Jun 2015 14:58:24 +0900 (KST)

----- 원본 메일 -----

보낸사람: "NutritionRP" <[nutritionrp@daum.net](mailto:nutritionrp@daum.net)>

받는사람: "Metzgar, Catherine J" <[metzgar2@illinois.edu](mailto:metzgar2@illinois.edu)>

날짜: 2015년 6월 09일 화요일, 11시 51분 01초 +0900

제목: RE: RE: Permission to reprint

Dear. Dr. Metzgar, Catherine J

We are under discussion for that part.

We will give a reply as soon as possible.

Sincerely,

Editorial office of NRP

----- 원본 메일 -----

보낸사람: "Metzgar, Catherine J" <[metzgar2@illinois.edu](mailto:metzgar2@illinois.edu)>

받는사람 : "'nutritionrp@daum.net'" <[nutritionrp@daum.net](mailto:nutritionrp@daum.net)>

날짜: 2015년 6월 09일 화요일, 04시 29분 21초 +0900

제목: RE: Permission to reprint

Hello,

Please see my previous request below. How should I proceed? Any advisement is much appreciated.

Ms. Catherine Metzgar

---

**From:** Metzgar, Catherine J  
**Sent:** Monday, June 01, 2015 11:39 AM  
**To:** 'nutritionrp@daum.net'  
**Subject:** RE: Permission to reprint

Hello,

Do you have any further response to this request?

Thanks.

**From:** Metzgar, Catherine J  
**Sent:** Friday, May 29, 2015 8:41 AM  
**To:** [nutritionrp@daum.net](mailto:nutritionrp@daum.net)  
**Subject:** RE: Permission to reprint

The final file is attached. What I would like to do for my dissertation is to include the paper as a text file only. A statement would be included to state that the paper had been previously published in it's an entirety.

Here is an examples: This article previously appeared in its entirety as Metzgar CJ, Preston AG, Miller DL, Nickols-Richardson SM. Facilitators and barriers to weight loss and weight loss maintenance: a qualitative exploration. *J Hum Nutr Diet*. 2014 Sept 18. doi: 10.1111/jhn.12273. [Epub ahead of print]. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is noncommercial and no modifications or adaptations are made.

Does your journal have any statement like this that should be made.

Thank you,

Ms. Catherine Metzgar, RD

**From:** [nutritionrp@daum.net](mailto:nutritionrp@daum.net) [<mailto:nutritionrp@daum.net>]

**Sent:** Friday, May 29, 2015 6:57 AM

**To:** Metzgar, Catherine J

**Subject:** RE: Permission to reprint

Dear Sir,

Reprints will not print again.

Can you send the final file?

If you have any other questions, please contact us.

Sincerely,

Editorial office of NRP

----- 원본 메일 -----

보낸사람: "Metzgar, Catherine J" <[metzgar2@illinois.edu](mailto:metzgar2@illinois.edu)>

받는사람 : "[nutritionrp@hanmail.net](mailto:nutritionrp@hanmail.net)" <[nutritionrp@hanmail.net](mailto:nutritionrp@hanmail.net)>

날짜: 2015년 5월 28일 목요일, 09시 49분 20초 +0900

제목: Permission to reprint

As I am putting my dissertation together, I would like to request permission to reprint the following paper of research that I conducted as a graduate student. Can you please advise on how to obtain permission to reprint?



Nickols-Richardson SM, Piehowski KE, Metzgar CJ, Miller DL, Preston AG. Changes in body weight, blood pressure and selected metabolic biomarkers with an energy-restricted diet including twice daily sweet snacks and once daily sugar-free beverage. Nutr Res Pract. 2014 Dec;8(6):695-704.

Thanks for your help.

Catherine Metzgar, RD  
Doctoral Candidate  
University of Illinois at Urbana-Champaign

Nutrition Research and Practice 편집국

e-mail: [nutritionrp@hanmail.net](mailto:nutritionrp@hanmail.net)

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**From:** Metzgar, Catherine J [<mailto:metzgar2@illinois.edu>]

**Sent:** Monday, May 11, 2015 1:25 PM

**To:** Geary, Daniel - Boston

**Subject:** Permission to reprint

Hi Daniel,

As I am putting my dissertation together, I would like to request permission to reprint the following paper of research that I conducted as a graduate student. Can you please advise on how to obtain permission to reprint?

Metzgar CJ, Preston AG, Miller DL, Nickols-Richardson SM. Facilitators and barriers to weight loss and weight loss maintenance: a qualitative exploration. *J Hum Nutr Diet*. 2014, Sep 18. doi: 10.1111/jhn.12273. [Epub ahead of print]

<http://www.ncbi.nlm.nih.gov/pubmed/25231461>

Thanks for your help.

Catherine Metzgar, RD  
Doctoral Candidate  
University of Illinois at Urbana-Champaign