

Daily Self-Monitoring During the Winter Holiday Period: A Strategy for Holiday Weight Maintenance in Reduced-Obese Older Adults?

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ABSTRACT

Weight management is problematic among Americans, as the number of overweight adults has risen to two-thirds of the population (1). Without the identification of successful approaches to promote weight stability, it is predicted that 86% of American adults will be overweight or obese by 2030 (2). Body-weight influenced diseases, such as diabetes and cardiovascular disease, are now leading causes of death (3). Annually, adult Americans are thought to increase their body weight by 0.5-0.9 kg (4). Of this gain, 52% is believed to occur during the winter holiday period of mid-late November to early January (5). Unfortunately, obesity research specific to this high-risk period is limited. Older adults and weight-reduced individuals are thought to be highly susceptible to significant holiday body weight gains (1, 6). To date, little research has investigated effective interventions that may be used to assist in successful body weight maintenance during the winter holiday period. Therefore, our purpose was to determine if daily self-monitoring of body weight, physical activity, and step counts is a feasible and effective tool to prevent weight gain in older, weight-reduced adults during the winter holiday period. This intervention represents a holiday weight maintenance approach that may be translatable to larger, more diverse populations.

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CHAPTER 1: Introduction

The overweight-obesity epidemic in the United States has grown to comprise 67% of adults and 33% of adolescents (1, 2). Clearly, weight management is challenging, as less than half of the American population can successfully maintain a healthy weight (3). Over the past several decades, Americans have struggled to maintain healthy weights and have been unsuccessful in reversing the rising trend of overweight and obesity (4).

The presence of excess weight is strongly associated with chronic medical conditions including: hyperlipidemia, cardiovascular disease (CVD), diabetes, hypertension, metabolic syndrome, sleep apnea, and certain forms of cancer (5). Due largely to the rise in obesity, CVD is the leading cause of death in the United States; this is unfortunate because many cases are preventable (6). Furthermore, the continued rise of overweight-obesity will decrease the quality of life and longevity.

Overweight and obesity may be defined in several ways. An overweight or obese body weight status is indicated by a body mass index (BMI) of 25-29.9 kg/m² (overweight) or 30 kg/m² or higher (obese); having a waist circumference (WC) of greater than 35 inches as a woman or greater than 40 inches as a man; having greater than normal skinfold measurements, or having a 35% or 41% body fat or higher as a woman or 23% or 29% body fat or higher as a man (overweight vs. obese, respectively), as calculated by dual energy x-ray absorptiometry (DEXA), underwater weighing, bioelectrical impedance analysis, or other means (7, 8). For the purposes of this thesis, overweight and obesity are defined using BMI criteria.

Among adults, weight management is particularly problematic for older adults (aged ≥ 60 years), as they have the highest prevalence of overweight and obesity (1). Approximately 78% of men and 69% of women aged 60 years or greater are overweight or obese (1). Older adults

are closely followed by middle-aged adults (aged 40-59 years), who have the second highest prevalence (1). Because of this, it is clear that older adults are a high-risk group for body weight gain.

Every year, individuals are thought to increase their body weight by 0.5-0.9 kg (9). While weight maintenance appears difficult for many adult populations, it is even more challenging for individuals who have previously undergone weight loss. For those successful in achieving weight loss, weight loss maintenance (WTLM) is a significant challenge, as nearly all individuals regain most or all of lost weight within five years (3). Only 20-37% of weight-reduced individuals are effective in maintaining 5-10% of lost weight (10, 11). Although there is not an established criterion for what constitutes successful WTLM, some have suggested the criterion of maintaining at least a 10% weight loss for at least one year, while others use a change of no more than 2% or 5% of body weight (12-14).

The struggle for successful weight maintenance is attributed to a variety of factors including: sugar-sweetened beverage consumption, fast-food restaurants, physical inactivity, high caloric intake, stress, and others (5, 15, 16). Surprisingly, over half of one's yearly weight gain is believed to occur during the brief winter holiday period of mid-late November to early January (17). Many of the aforementioned weight gain contributors are particularly abundant during the winter holiday period, making it a high-risk period that warrants attention (18, 19). The weight gained during this holiday period has been found to average from 0.32 kg to over 1.0 kg (17, 20). During the five-day Christmas period alone, weight may increase 0.93 kg, with gains as much as 4 kg reported (21). The amount of weight gained during the winter holiday months is concerning, as the amount of weight gained compared to the short duration of the holiday period is drastic when compared to yearly weight gains (21).

Unfortunately, obesity research specific to the winter holiday period is scarce. Previous investigations have determined that weight-reduced or overweight-obese individuals, as compared to normal weight individuals, are at greater risk for holiday weight gain (18). Additionally, weight-reduced and overweight-obese individuals are less likely than normal weight counterparts, to recover from body weight gained during the winter holiday period (18). Thus, there is a need to determine effective weight management strategies specific to the winter holiday period, particularly among weight-reduced individuals (17). To date, no studies have investigated effective weight management interventions that could successfully promote weight stability during the holidays; although, one study has reported that consistent self-monitoring during the winter holiday period helps participants lose weight (22, 23).

While many interventions and strategies to promote successful weight management have been studied during the non-holiday months, these techniques have not been studied related to their feasibility during the winter holiday period. Research has demonstrated the effectiveness of daily self-monitoring of body weight in the prevention of weight gain (11, 24-26). The feasibility of this intervention is questioned because of the high stress, busy nature of the time period.

It is clear that healthy weight maintenance is problematic for all ages and populations of Americans. Without effective weight management strategies and interventions, the obesity epidemic will continue to rise to incorporate most Americans. While weight appears to be gained throughout the year, the contribution of the winter holiday period cannot be overlooked. Because more than half of annual weight gain is acquired during this period, effective strategies must be developed to reduce weight gain (17). Individuals who have undergone weight loss and older adults are at greatest risk for weight gain, and, therefore, should be considered a priority

population. Daily self-monitoring of weight, physical activity, and dietary intake has been shown to successfully prevent weight gain during the non-holiday periods, but effectiveness of this technique during the holidays is unknown (11, 27). Future studies are needed to further assess the effectiveness of daily self-monitoring as a holiday weight management strategy for highly susceptible populations, as well as larger populations in general.

The purpose of this investigation is to determine the feasibility and effectiveness of a weight management intervention that consists of daily self-monitoring of body weight, physical activity, and fruit and vegetable intake during the winter holiday period. The target population is weight-reduced older adults; both weight-reduced status and age are associated with increased risk of weight gain. We hypothesize that participants will be compliant, defined as $\geq 75\%$, with daily self-monitoring of body weight, thus indicating feasibility. In addition, we hypothesize that this intervention will be effective in preventing holiday weight gain, defined by a gain of <0.7 kg. This criterion was selected based upon a previous investigation of individuals in a stage of WTLM, which reported that participants increased body weight by 0.7 kg during the winter holiday period (18). If successful, this intervention approach could be the first to identify a feasible and effective weight-loss maintenance strategy during the winter holiday period.

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CHAPTER 2:

Daily Self-Monitoring During the Winter Holiday Period: A Strategy for Holiday Weight Maintenance in Reduced-Obese Older Adults?

ABSTRACT

Weight gained during the winter holiday months account for more than half of annual weight gain. Obese and reduced-obese individuals are at increased risk for holiday weight gain, and recovery from holiday weight gain is particularly problematic among reduced-obese individuals. Previous work has determined that daily self-monitoring of body weight can improve weight loss maintenance; therefore, the objective of this investigation was to determine the feasibility and effectiveness of a winter holiday behavioral weight management (WM) intervention on weight loss maintenance in reduced-obese older adults.

Intervention (INT) group participants were reduced-obese middle-aged and older adults (n=23; aged 63±1 yrs; BMI 29.1±1.1 kg/m²; wt lost=7.5±0.8%) enrolled in a WM intervention consisting of daily self-monitoring (body weight, step counts, fruit/vegetable intake) using tracking sheets, which were submitted to the study coordinator each week. Weight was assessed for INT participants at baseline (Oct. 12-22), post-holiday (Jan. 5-14), and at follow-up (Feb. 16-26). Weight was assessed in control (CON) group participants (n=25; age 63±1 yrs; BMI 31.3±0.7 kg/m²) at each of these time periods; CON participants were not provided with instructions for self-monitoring weight, diet, or physical activity.

INT group compliance with submission of the tracking sheets over the 12-week holiday period (Oct. 12-Jan. 4) was 77.0±0.5%. During this study period, CON participants gained 0.8±0.3 kg, representing a body weight change of 1.0%. INT participants gained 0.4±0.3 kg,

which represented a body weight change of 0.5%. Mean body weight increased over time among all participants ($P=0.028$).

The daily self-monitoring program minimized a holiday weight gain, as compared to that previously reported, although statistically significant group differences were not detected in weight gain ($P=0.37$). The reasonably high level of compliance suggests this approach is feasible; future studies including larger sample sizes are warranted.

KEY WORDS

Holiday, weight loss maintenance, self-regulation, reduced-obese, self-monitoring

INTRODUCTION

It is estimated that by the year 2030, 86% of Americans will be overweight or obese (1). These adverse changes in body weight status have been a challenge for decades (2). Weight management is particularly problematic for older adults (aged ≥ 60 years), as greater than three-fourths of men and two-thirds of women in this age group are overweight or obese (2). Compared to all age groups, older adults have the highest prevalence of overweight or obesity, closely followed by middle-aged adults (aged 40-59 years) (2).

For weight-reduced individuals, weight loss maintenance is a significant challenge, as many successful weight losers are unable to maintain most or any of their lost weight after five years (2, 3). In fact, only about one-third of individuals who have lost weight are effective in maintaining 5-10% of the total weight lost (4, 5). One strategy which may reduce the risk of weight gain or regain is daily self-monitoring of body weight (5-8).

Contributors to weight gain/regain include: lack of portion control, sugar-sweetened beverage consumption, increased meals outside of the home, lack of physical activity, overconsumption of calories, genetic factors, and stress (9, 10). Many of these weight control obstacles are particularly evident during the traditional United States winter holiday period, which is typically considered to be mid-late November to early January (11, 12).

The amount of weight gained annually varies across individuals, but has been estimated to be 0.5-0.9 kg (13). Importantly, 52% of this yearly weight gain is thought to be accrued during the winter holiday period alone (14). Studies of holiday weight gain report increases ranging 0.4 kg to ≥ 1.0 kg (14, 15). Weight increased by 0.9 kg, with some individuals gaining as much as 4.0 kg, during the five-day Christmas period alone (16). An investigation of reduced-obese individuals in a stage of weight loss maintenance (WTLM) reported a mean weight gain of

0.7 kg from early November to early January, from which they were unable to recover (11). Holiday weight management poses a greater challenge to adults that are currently or previously overweight or obese (14). As compared to normal-weight individuals, overweight and obese individuals gain five times more weight during the Thanksgiving holiday alone (15). Weight maintenance may also be difficult for individuals that diet very strictly during the year, but are lenient during holiday periods; these individuals gain almost twice as much weight as those who maintain consistent diets (17). Thus, the winter holiday months are a period of amplified risk for weight gain, as overconsumption of calories and/or lack of physical activity may be common (14, 18).

Previous investigations have demonstrated that daily self-monitoring of body weight can facilitate weight management; yet, research specific to the holiday period is limited (11, 19, 20). In addition, the high-stress and busy nature of the holiday period questions the feasibility of an intervention (21). Therefore, the purpose of this investigation was to determine if daily self-monitoring of body weight, physical activity, and fruit and vegetable intake is a feasible and effective approach for preventing holiday weight gain, among weight-reduced older adults.

MATERIALS AND METHODS

Participants

Intervention group participants (INT; n=23) had recently completed a 12-week weight loss (mean weight loss of 6.9 ± 0.8 kg, $7.5 \pm 0.8\%$ of initial body weight) program for middle-aged and older adults, and were enrolled in a 12-month weight loss maintenance (WTLM) intervention (mean duration of WTLM prior to enrollment = 102 ± 11 days). Control participants (CON; n=25) were recruited from the local community through electronic and

newspaper advertisements. Prior to enrollment, individuals underwent a telephone and laboratory-based screening process to determine study eligibility. Inclusion criteria were as follows: 55-75 years of age, overweight or obese ($BMI \geq 25 \text{ kg/m}^2$) (for INT, prior to weight loss), weight stable ($\pm 3 \text{ kg}$, $>1 \text{ year}$, CON only), and non-smokers. Individuals were excluded if they had uncontrolled hypertension ($SBP > 160 \text{ mmHg}$ and/or $DBP > 100 \text{ mmHg}$), diabetes, cancer, heart disease, lung disease, kidney disease, clinical depression (Centers for Epidemiological Studies Depression Scale ([CES-D] score < 35) (22), or were currently or previously (within 6 months) taking medications that could affect weight status or appetite. Control participants were informed that the study was investigating health outcomes during the winter holiday season, but they were not aware of the exact study purpose. The Virginia Polytechnic Institute and State University Institutional Review Board approved the study protocol and all participants provided written, informed consent. An overview of the study design is provided in Figure 1.

Protocol

INT participants were instructed to complete weekly self-monitoring (i.e., tracking) logs, which included daily recording of body weight (lbs), physical activity (step counts), and fruit and vegetable intake (servings). To measure body weight, INT participants were provided with a digital scale for home-use (Tanita HD350, Tanita Inc., Arlington Heights, IL). Physical activity was measured by total daily step counts through the use of a pedometer (ACCUSPLIT Eagle AX120, San Jose, CA). INT participants were educated on serving size determination (23) to assist in recording daily fruit and vegetables servings. INT participants were deemed compliant if 75% of the weekly tracking sheets were completed and returned to the study coordinator.

Program and individual goals were established to motivate and guide INT participants, for which they received weekly feedback upon submission of their tracking sheet. Upon receipt of the tracking log, the study coordinator sent participants tailored feedback addressing the participant's goal or adherence to the program goals. Adherence to each program goal was evaluated and deemed successful if the participant: a) submitted the tracking log within one week of completion, b) adhered to the weight goal of ≤ 3 pounds of baseline reduced weight, c) adhered to the steps (physical activity) goal of $\geq 10,000$ steps per day (24), and d) adhered to the fruit and vegetable goal of ≥ 5 servings per day (23). Tracking log data was evaluated over the holiday time period (Oct. 12-Jan. 4). Body weights, measured in the laboratory, and food records, were assessed monthly throughout the study; step count records were reported continuously in INT participants. To assess group differences in step counts, seven day average values were evaluated at the baseline and follow-up time periods.

CON participants were asked to maintain their usual behaviors, and were not provided with nutrition or health counseling until completion of the study. CON participants attended one laboratory session at baseline (October 12-22), post-holiday (January 5-14), and at a follow-up (February 16-26). Body weight was measured at each session. CON participants completed a 4-day food record and a 7-day step count record prior to the baseline and follow-up session. Upon completion of the follow-up session, CON participants were debriefed informed of the true purpose of the study, and compensated with a \$25 gift card.

Procedures

Anthropometric measures. Height (m) was measured without shoes using a wall mounted stadiometer. Weight was measured, to the nearest 0.1 kg, without shoes and in light street

clothes, using a digital scale (Scale-tronix 5002, White Plains, NY). Initial height and weight were used to calculate BMI (weight (kg)/height (m)²).

Dietary intake. Self-reported dietary intake was assessed using a 4-day food record, which consisted of four consecutive days with at least one day being a weekend day. A trained technician instructed participants on the appropriate methods for recording food and beverage intake. To enhance recording accuracy, participants were provided with two-dimensional food diagrams to assist in portion size determination. Each record was reviewed for completion upon return. Nutrition analysis software (NDS-R 4.05, 2009, University of Minnesota, Minneapolis, MN) was used to analyze the food records.

Physical activity. Participants were provided with a pedometer (ACCUSPLIT Eagle AX120, San Jose, CA) to measure total daily step counts. They received instruction on handling prior to usage, and were asked to record daily step counts on step count logs when pedometers were worn.

Health History Questionnaire (HHQ). The HHQ was used to determine eligibility; questions included previous and current medical conditions, medication usage, success of weight control, and weight history.

Data Analysis

SPSS (v.12.0 for Windows, 2003, Chicago, IL.) analysis software was used to perform statistical analyses. Independent sample t-tests were used to assess group differences at baseline in age, height, BMI, and weight. Repeated measures ANOVA was used to assess group differences in step count, body weight, and body weight changes, over time. When significant differences were detected, t-tests were used for post-hoc analyses. Differences in frequency variables were assessed using a chi-square analysis, and a Box's test assessing homogeneity of

variance was used to evaluate differences in weight variability over the study period. Data are expressed as mean \pm SEM.

RESULTS

There were no baseline differences between groups with respect to BMI, age, height, weight, or gender representation (Table 1). Participants were predominantly female (63%) and Caucasian (96%). Outcomes in the two groups over the three assessment periods (baseline, post-holiday, follow-up) are presented in Table 1. No significant group by time differences existed in weight (kg) across holiday periods ($P=0.604$). However, mean body weight increased over time.

As shown in Figure 2, CON participants gained 0.8 ± 0.3 kg, representing a body weight change of 1.0%, and INT participants gained 0.4 ± 0.3 kg, representing a body weight change of 0.5%. However, differences in weight change were not statistically significant between groups ($P=0.37$). Weight gain recovery during the follow-up period was not different between groups ($P=0.79$).

Differences in weight change status was compared in the two groups for the 12-week period, as follows: losers (lost <0.0 kg) (INT: $n=8$, CON: $n=6$), weight gainers (gained ≥ 0.7 kg) (INT: $n=12$, CON: $n=14$), and weight stable individuals (gained $0\leq x\leq 0.69$ kg) (INT: $n=3$, CON: $n=5$). Group differences in frequency of weight losers/gainers/stable individuals was not found ($\chi^2= 0.85$, $df=2$, $P=0.65$).

Reductions over time in mean seven-day step counts were noted among all participants (Table 1). Fat gram intake was significantly lower in INT verses CON group. For the 12-week holiday period, INT group compliance to the submission of the weekly tracking logs was

77.0 \pm 0.5% and adherence to the weight goal, step goal, and fruit/vegetable goal were 84.8 \pm 0.5%, 60.5 \pm 0.7%, and 71.7 \pm 0.6%, respectively.

DISCUSSION

The contribution of the winter holiday period to annual weight gain appears significant, and holiday weight gain is particularly problematic for reduced-obese individuals. However, the strategies to address this weight management challenge are unknown. This preliminary investigation determined that a daily self-monitoring intervention is a feasible approach which may be used to minimize holiday weight gain.

These findings represent the first holiday weight gain intervention study specifically targeting reduced-obese, older adults. Due to the high prevalence of overweight and obesity among older adults, weight management interventions targeting this population group are warranted. Importantly, weight gain reported in this investigation is comparable to larger-scale holiday studies. The simple recording procedure represents a low-resource intervention approach to curtailing holiday weight gain, which may save time and financial resources for individuals. The following limitations of the current study are acknowledged. First, the sample size was small, primarily Caucasian, and restricted to older adults. Thus, the application of these findings to other age ranges or more varied population groups may be limited. Although the small sample size likely limited the statistical power to detect differences in weight gain, this preliminary study may be used to determine sample sizes needed for future studies on this topic. Using these findings (group differences, standard deviations), it is estimated that future investigations would require a sample size of approximately 250 participants (125/group), in order to detect significant group differences given the small-medium effect size of 0.26. Second,

it is recognized that self-reported data, such as the self-reported body weights, step counts, and fruit and vegetable consumption in the intervention group, may be subject to recording error. Third, the control group did not consist of reduced-obese individuals, who may have demonstrated higher levels of holiday weight gain.

Given trends in weight gain that have occurred in recent decades, it is crucial successful approaches to weight management during the holiday period are addressed in order to enable public health messages, governmental policies, and health professionals to target the factors that effectively minimize weight gain. These findings suggest that daily self-monitoring of body weight, diet, and physical activity is a feasible, and potentially effective, approach for minimizing weight gain over the winter holiday period. Future studies with larger sample sizes are warranted to further evaluate this approach.

Table 1. Results: Daily self-monitoring during the winter holiday period as a strategy for weight loss maintenance in middle-aged and older reduced-obese individuals and control participants.*

Variables	Intervention Group (n=23)			Control Group (n=25)		
	Baseline	Post-Holiday	Follow-Up	Baseline	Post-Holiday	Follow-Up
Age, years	63±1	-----	-----	63±1	-----	-----
Male/Female, n	9/14	-----	-----	9/16	-----	-----
BMI, kg/m ²	29.1±1.1	-----	29.3±1.2	31.3±0.7	-----	31.5±0.7
Weight, kg ^a	81.4±3.3	81.8±3.4	81.7±3.3	85.6±2.9	86.4±2.9	86.4±2.8
Height, cm	167.2±2.1	-----	-----	165.2±1.7	-----	-----
Steps Counts, 7 day average ^a	8208±467	-----	7275±504	7153±769	-----	5828±590
Dietary Intake:						
Calories, kcals/day	1589±107	-----	1639±87	1830±103	-----	1819±94
Fat, grams/day ^b	53±5	-----	53±5	72±6	-----	73±5
Carbohydrates, grams/day	196±11	-----	209±11	208±14	-----	208±13
Protein, grams/day	72±7	-----	72±4	77±5	-----	110±36
Alcohol, grams/day	11±3	-----	11±3	9±3	-----	10±3
Fruit/Vegetables, servings/day ^c	4.9±0.2	4.9±0.2	-----	N/A	N/A	N/A

Baseline (Oct. 12-22); Post (Jan. 5-14); Follow-Up (Feb. 16-26)

*Presented as mean ±SEM, for continuous variables.

^aSignificant differences detected over time for the full sample ($P<0.05$).

^bSignificant difference between groups at baseline and follow-up ($P<0.05$).

^cAssessed using self-reported tracking sheets; other dietary intake variables were assessed using food intake records at baseline and follow-up.

Figure 1. Study design.

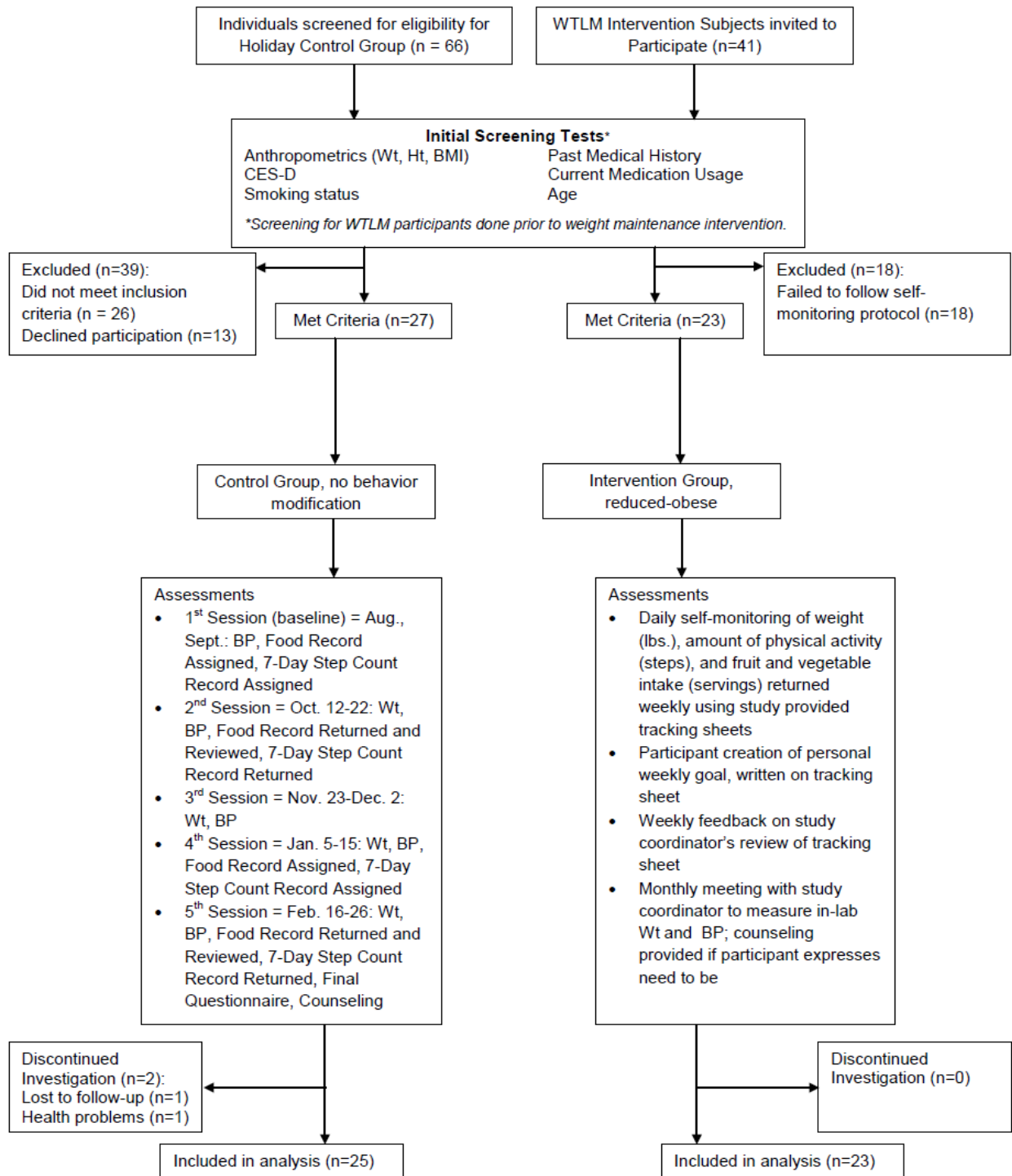
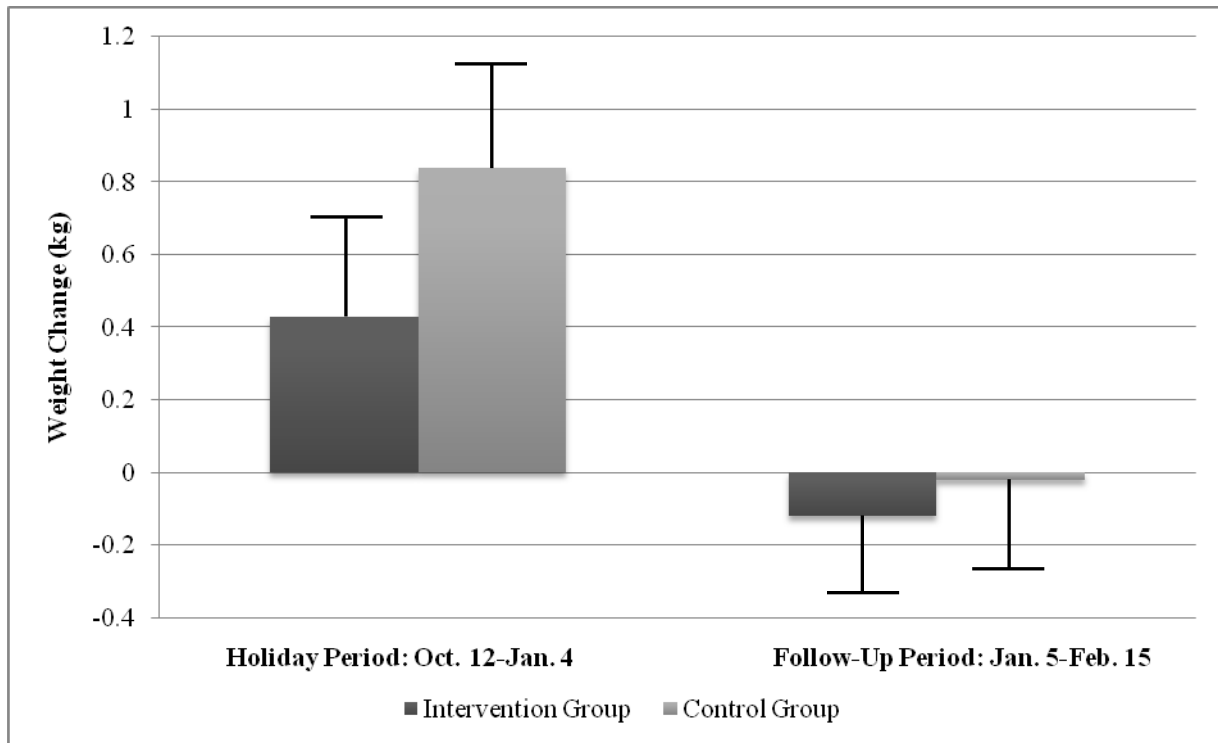


Figure 2. Weight change during the 12-week holiday period and the post-holiday follow-up period among reduced-obese adults participating in a daily self-monitoring intervention, and in control participants.



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CHAPTER 3:

Conclusions and Implications for Future Research

The significant contribution of body weight increases during the winter holiday period to that experienced annually is evident (1). While weight gains are observed in all populations, weight-reduced and overweight or obese individuals are at highest risk; the greatest weight increases and lowest ability to recover are found in these populations (1, 2). The purpose of this study was to determine the feasibility and effectiveness of a winter holiday weight management intervention emphasizing daily self-monitoring in weight-reduced older adults. The intervention group daily self-monitored body weight, physical activity, and fruit and vegetable intake; the control group had no behavior modification. The intervention group experienced a mean increase in body weight of 0.4 kg, while the control group experienced a mean increase of 0.8 kg. The findings of this study indicate that daily self-monitoring of body weight, physical activity, and food intake is a feasible and potentially effective strategy to minimize holiday weight gain. However, the lack of research available on weight management during the winter holiday period leaves many unanswered questions. Additional research is needed to address the translatability, cost, and other factors that affect the implementation of the intervention into a real-world setting.

Currently, little is known about the translation potential of many WTLM interventions into practice (3). Therefore, a future direction for this project is to explore the translatability of the intervention into real-world situations. One way to do this is to examine this intervention in the terms of the RE-AIM framework (reach, efficacy/effectiveness, adoption, implementation, and maintenance) (3). The application of this framework to the holiday daily self-monitoring

intervention could help interpret the translation ability of this weight management strategy by helping to identify strengths, weaknesses, and areas for improvement (3).

Because the application of clinical research findings to real-world situations is lacking, strategies to successful translation need to be identified (3). One approach that could be considered to implement this intervention in a community or population of people is through the use of community based participatory research (CBPR). CBPR is a collaborative approach to research that involves shared decision making and participation between the community and the researchers (4). This approach strives to increase the capacity and knowledge of the community to best carry out and sustain a behavioral modification in the community (4). Working with a community to further determine the best approaches and hindrances to daily self-monitoring during the winter holiday period, could help us to develop a more effective and feasible strategy to target specific health disparate populations.

This weight management intervention was primarily limited to Caucasian women who were currently or previously overweight or obese. A review of weight management research emphasizing self-monitoring found that this population of individuals is the primary population represented in self-monitoring interventions (5). Because of this, there is a need to study the feasibility and effectiveness of this intervention in racially and gender diverse populations, specifically African Americans and males. Additionally, research from the National Weight Control Registry indicates that older adults may be more successful at self-monitoring their body weight than other age groups (6). Thus, it is important to also determine the effectiveness of this intervention in all age groups. Should this holiday weight management intervention not be successful in other populations, a CBPR project may be helpful in determining other approaches that may be feasible and effective.

Part of evaluating this weight management strategy's translation potential into a variety of populations, also includes determining the cost of the intervention. While the project was low-resource, the exact cost of it is currently unknown. Recent research reviews have been performed on diabetes interventions, including self-monitoring interventions, to illustrate costs, benefits, and usefulness of different strategies; however, no economic analyses performed on weight-management interventions could be identified, and none exist that specifically pertain to strategies during the winter holiday period (7). It would be further beneficial to determine the cost-benefit ratio of this intervention (7). The cost-benefit ratio could illustrate that even if the intervention cost may be higher than expected, the benefit costs may outweigh the expense costs (7). Understanding the costs and benefits associated with this holiday weight management strategy would help health care organizations, employers, and other populations to determine if it is beneficial for them, while allowing costs and benefits of other strategies to be compared.

In addition to translation and cost, it may be important to evaluate the different tools available to self-monitor, as they may affect the translatability, effectiveness, feasibility, and cost of this intervention. Besides this study, the only other study specific to the winter holiday period that included self-monitoring used paper log sheets (8). In other self-monitoring projects, participants have used personal digital assistants (PDAs), the Internet, and other tools to record self-monitored variables (5, 9). The type of tool used can affect the comfort with use, social acceptability, convenience, and cost, which may in consequence affect adherence to the intervention (5). In fact, one study reported that the use of a PDA helped participants to successfully self-monitor body weight; participants reported that they felt it was a more socially acceptable way to self-monitor than other ways (5, 10). The tool used to self-monitor may affect the successfulness of self-monitoring in the population studied; therefore, it may be valuable to

determine the different feasibility and effectiveness rates achieved with tools other than paper logs.

Besides determining the various tools that could be used to increase feasibility and effectiveness of this winter holiday WTLM intervention, other low-resource approaches to holiday weight management should also be considered. While no other weight management strategies have been studied specific to the winter holiday period, several approaches have been found potentially effective during other periods. Interventions focusing on developing and maintaining a consistent eating pattern may be effective (11). A one-year longitudinal study found that individuals who diet more strictly on weekdays than on weekends and at holidays experience greater body weight increases than do individuals who maintain consistent diets; therefore, dieting consistently throughout the year has been thought to promote better weight management (11). Additionally, interventions focusing on achieving high levels of physical activity daily (one hour) have also been thought to be effective in WTLM (12). Thus, the development of interventions aimed at increasing daily physical activity levels may be important. Furthermore, the use of strategies that enhance stimulus control have been thought to be effective in weight management. Greater stimulus control and better WTLM has been demonstrated in interventions that target to increase behaviors, such as eating breakfast, planning meals, increasing dietary restraint, and counting calories consumed (2, 11-14). It is essential that additional body weight management strategies specific to the winter holiday period be explored, as the feasibility and effectiveness of this daily self-monitoring intervention in diverse populations is unknown.

Pertaining to this winter holiday weight management intervention and future interventions developed, it is important that contingency plans be determined to address and limit

lapses or relapse during and post-intervention. Determining such strategies will help to increase the translation potential of the intervention (3). Only 11% of people are thought to successfully recover from minor lapses of 1-2 kg; therefore, it is crucial that contingency plans are developed to promote better long-term weight management (14). In this winter holiday weight management intervention, INT participants were asked to set weekly goals, in addition to the daily self-monitoring protocol, to help maintain motivation. Continued motivation is thought to be a crucial component in preventing and recovering from lapses (15). Other weight management interventions have suggested that strategies to increase accountability, like those promoting group involvement or partnership formation, contact with a health professional or researcher post-intervention, confidence and perceived control enhancement, and attendance at weight management classes, may be necessary to prevent and assist in recovery from lapses (16). It is important that the effect of goal setting in this winter holiday study on the potential prevention and recovery from INT group lapses be determined, in order to enhance the intervention's translation potential and to help guide future studies in the development of contingency plans.

Another future direction that needs to be explored in the weight management literature is the level of adherence to a self-monitoring weight management intervention that is needed for successful outcomes (5). Currently, there is no established level. In this intervention, adherence to the daily self-monitoring was 77%, reasonably high. Self-monitoring of body weight appears to be more effective as the frequency of weighing increases; therefore, daily weighing produces better weight management than weekly weighing (5, 17). However, there is no consensus among the literature on the definition of successful self-monitoring for weight management. In the medical literature, successful adherence to self-monitored or self-reported medication intake varies by definition; some studies reported a minimum of 50% or 60% adherence as successful,

while others reported a minimum of 80% adherence as successful (18-21). A standard criterion of adherence must be established in order to evaluate weight management interventions more effectively and objectively.

Lastly, a review of all weight management research evaluating self-monitoring interventions found that there is strong evidence in favor of the effectiveness of using self-monitoring of body weight and dietary intake, but the usefulness of self-monitoring of physical activity is less known (5). Because of this, future studies may want to work to determine which variables must be self-monitored to create a successful, effective, and feasible intervention (i.e. only weight, physical activity, or food, or a combination of variables). Adherence to this holiday weight management intervention may have been affected by the inclusion of three variables to self-monitor, instead of one or two; this would be interesting for future research to address.

In conclusion, this low-resource weight management intervention represents a feasible and potentially effective approach to limiting body weight gains during the winter holiday period. The tracking methodology of this strategy provides individuals with accountability, which may increase its effectiveness and translation potential (4). Prior weight management research indicates that as the length of time of a self-monitoring program increases, the adherence to the self-monitoring protocol decreases (5). Thus, given the established effectiveness of daily self-monitoring interventions over longer periods of time, it may be particularly effective during the short winter holiday period. The translation potential, cost, and tools used to self-monitor are all important factors of the current weight management intervention that need to be explored further. Additionally, while adherence to the daily self-monitoring regimen was high, there is no definition of successful adherence to a weight management intervention to compare it to; therefore, it is not clear how adherence of this

intervention may compare to others. Future studies are needed to examine the effectiveness and feasibility of this holiday weight management approach in larger, more diverse populations, while working to make this strategy translatable to diverse populations.

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FWA00000572(expires 1/20/2010)
IRB # is IRB00000667

DATE: August 18, 2009

MEMORANDUM

TO: Brenda M. Davy
Jeremy Akers
Rachel Cornett

Approval date: 8/18/2009
Continuing Review Due Date:8/3/2010
Expiration Date: 8/17/2010

FROM: David M. Moore 

SUBJECT: **IRB Expedited Approval:** "Holiday Health Status Among Older Adults" , IRB # 09-663

This memo is regarding the above-mentioned protocol. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. As Chair of the Virginia Tech Institutional Review Board, I have granted approval to the study for a period of 12 months, effective August 18, 2009.

As an investigator of human subjects, your responsibilities include the following:

1. Report promptly proposed changes in previously approved human subject research activities to the IRB, including changes to your study forms, procedures and investigators, regardless of how minor. The proposed changes must not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
2. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
3. Report promptly to the IRB of the study's closing (i.e., data collecting and data analysis complete at Virginia Tech). If the study is to continue past the expiration date (listed above), investigators must submit a request for continuing review prior to the continuing review due date (listed above). It is the researcher's responsibility to obtain re-approval from the IRB before the study's expiration date.
4. If re-approval is not obtained (unless the study has been reported to the IRB as closed) prior to the expiration date, all activities involving human subjects and data analysis must cease immediately, except where necessary to eliminate apparent immediate hazards to the subjects.

Important:

If you are conducting **federally funded non-exempt research**, please send the applicable OSP/grant proposal to the IRB office, once available. OSP funds may not be released until the IRB has compared and found consistent the proposal and related IRB applicaton.

cc: File

Invent the Future



MEMORANDUM

DATE: July 19, 2010

TO: Brenda M. Davy, Jeremy Akers, Rachel Cornett

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires June 13, 2011)

PROTOCOL TITLE: Holiday Health Status Among Older Adults

IRB NUMBER: 09-663

Effective August 18, 2010, the Virginia Tech IRB Chair, Dr. David M. Moore, approved the continuation request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at <http://www.irb.vt.edu/pages/responsibilities.htm> (please review before the commencement of your research).

PROTOCOL INFORMATION:

Approved as: **Expedited, under 45 CFR 46.110 category(ies) 4, 5, 7**

Protocol Approval Date: **8/18/2010 (protocol's initial approval date: 8/18/2009)**

Protocol Expiration Date: **8/17/2011**

Continuing Review Due Date*: **8/3/2011**

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals / work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

Date*	OSP Number	Sponsor	Grant Comparison Conducted?

*Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this IRB protocol is to cover any other grant proposals, please contact the IRB office (irbadmin@vt.edu) immediately.

cc: File

Appendix B: Telephone Screening Form

Name _____ Date _____ Interviewer _____
Address _____ Phone (H) _____ Availability: _____
_____ (W) _____

Age _____
*must be 55-75 yrs

Height _____ (in) x 2.54 = _____ (cm) / 100 = _____ (m) **BMI** _____ kg/m²
Weight _____ (lbs) / 2.2 = _____ (kg) *must be ≥ 25 and ≤ 47

Are you currently weight stable (within about 5 pounds of current weight for past year?) _____
Have you participated in a formal weight loss program within the last year, or are you currently participating in such a program? _____ (if so, not eligible)
Are you a smoker? N ___ Y ___ *must be weight stable and nonsmoker to participate

Current Medications (including over the counter):

Do you have a history of diabetes, heart, lung, or kidney disease, thyroid problems or cancer?
N ___ Y (explain) _____
Do you have a history of eating disorders or depression? N ___ Y (explain) _____

Past Medical History:

Do you use hormone replacement therapy? N ___ if Y, how long _____

This is study investigating holiday health status study in older adults, which would involve 5-6 visits to the Virginia Tech campus over ~ 4 months. At each visit, your height, weight, blood pressure, and pulse will be measured. You will also be asked to complete health questionnaires at each visit. Additionally, you will be asked to record your daily food intake for four consecutive days and your physical activity for seven consecutive days at the beginning of the study, and again at the end of the study. You will be provided with a pedometer to measure your physical activity level. You will receive a \$25 Kroger gift card upon completion of the entire study. All of the testing will be provided free of charge and you will receive health advice upon completion of the study.

Are you interested in participating? N ___ Y, schedule initial visit _____
*if yes: vehicle make _____ Model _____ License plate # _____

May we contact you for future studies? N ___ Y _____

Appendix C: Measured Variables

Subject ID: _____

Researchers Initials: _____

Date	Weight	Height	Blood Pressure	Pulse	CES-D, Food Record, Step count Form Given? (pre/post only)
Session 1:	_____ kg _____ lb	_____ in	_____	_____	HHQ ____ CESD ____ FIR ____ Step form ____
Session 2:	_____ kg _____ lb	_____ in	_____	_____	
Session 3:	_____ kg _____ lb	_____ in	_____	_____	
Session 4:	_____ kg _____ lb	_____ in	_____	_____	
Session 5:	_____ kg _____ lb	_____ in	_____	_____	FIR ____ Step form ____

Additional Notes:

Subject ID Number _____

Page ___ of ___

Date _____

Day (circle): 1 2 3 4 Other (indicate) _____

Appendix D: Food Intake Record

Line # (office use)	Time	Place	Food Description (Please specify, if known: brand names, cooking method, type of product, and include labels when possible)	Portion Size : How many?	Portion Size : Food Model	Thickness /Ice in drink	Office Use Only

Appendix E: Pedometer Step Count Tracking Log

Subject ID: _____

Instructions: Please record 7-consecutive days of daily pedometer step counts, beginning with the date you were assigned. We understand that you may miss a daily check so we ask that you be honest when recording.

1. Date _____

Daily Total Step Count _____

2. Date _____

Daily Total Step Count _____

3. Date _____

Daily Total Step Count _____

4. Date _____

Daily Total Step Count _____

5. Date _____

Daily Total Step Count _____

6. Date _____

Daily Total Step Count _____

7. Date _____

Daily Total Step Count _____

*Thank you for your honesty. Please submit this completed form to Rachel at your next visit.