Are There Sex Differences in Behavioral Predictors of Successful Weight Loss Maintenance?

Mary Elizabeth Baugh

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> Brenda M. Davy, Chair Kevin P. Davy Hollie A. Raynor Jyoti S. Savla

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ABSTRACT

Current literature emphasizes poor long-term weight loss maintenance (WTLM) outcomes, and the need for inexpensive, practical solutions for effective WTLM is evident. Individuals successful at WTLM utilize similar behaviors but in varying amounts and combinations, seemingly choosing behaviors that best fit their preferences. Researchers have attempted to identify characteristics of individuals that may predict successful WTLM in order to develop flexible WTLM treatments based on individuals' lifestyle and preferences.

The purpose of this analysis was to examine sex differences in WTLM outcomes and to identify potential behaviors related to WTLM success. In a 12-month study targeting WTLM, weight-reduced middle-aged and older men and women (n=39) were assigned behavioral goals for body weight, fruit and vegetable intake, water consumption, and physical activity and were asked to daily self-monitor body weight and these behaviors. Sex difference in clinically significant WL (≥5% WL) at 12 months was determined. A growth curve model assessed interactions of sex and WTLM predictors, and a crisp set qualitative comparative analysis (QCA) characterized individuals' weight changes and behaviors. No sex difference was found in clinically significant WL or in the interaction of sex and behaviors on weight change; however, QCA evidence suggests men and women may approach WTLM with different behaviors. Additionally, QCA findings suggest weight change in the first 3 months of WTLM may determine success at 12-months. WTLM treatments should provide more intensive support during the transition period from WL to WTLM. Future research in predictors of WTLM, particularly within the context of sex, is essential.

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CHAPTER 1: Introduction

Over 67% of American adults are overweight or obese, and research projects that this percentage will rise to nearly 90% over the next 15 years if the trend observed over the last 3 decades continues [1]. Obesity is an independent risk factor for many chronic conditions, including diabetes mellitus, hypertension, dyslipidemia, cardiovascular disease, and various cancers [2], and obesity is associated with increased mortality, especially from cardiovascular disease, diabetes mellitus, and certain cancers [3]. In fact, overweight and obesity is the second leading cause of death in the United States (US), following only smoking [4]. Consequently, obesity and obesity-related diseases place a huge financial burden on the country, costing about 10% of total medical spending in 2008 (likely as high as \$147 billion) [5]. The prevalence of obesity in men and women in the US is similar, with 32.2% of men and 35.5% of women being obese [3]. Therefore, finding inexpensive, practical solutions for effective weight loss (WL) and weight loss maintenance (WTLM) that can be implemented at the clinical practitioner level are essential [6, 7]. Both the health and economic benefits of successful WL and WTLM strategies are easy to foresee, but practical solutions have yet to be defined [6].

Current State of WTLM

Many people can benefit from only modest amounts of WL; a clinically significant WL of 5-10% body weight is associated with reductions in mortality and biomarkers for cardiovascular disease risk and type 2 diabetes mellitus [8]. Though there are a variety of treatment options targeting clinically significant WL (e.g., pharmacological treatment, surgical treatment, etc.), behavioral lifestyle treatments are the most widely used Through worksite intervention survey, Jeffery *et al.* [9] found that 47% of men and 75% of women diet to lose weight at some point during their lives, highlighting the prevalence of behavioral efforts toward WL.

Attempts at WL, particularly utilizing behavioral lifestyle methods, are largely successful, but long-term WTLM is difficult for most people. For many, weight cycling is a common occurrence; the high prevalence of relapse in WTLM (i.e., weight regain) has been likened to relapses experienced with treatments of alcohol or substance addiction or depression, and, like these conditions of chronic relapsing, WTLM requires vigilant monitoring and appropriate

management for long-term success [10]. It may be that altered physiology predisposes reduced-body weight individuals to relapse because energy requirements decrease after WL but energy intake behaviors related to hormonal changes persist; therefore, targeting behavioral control of energy balance is critical to addressing successful WTLM [10]. WTLM literature highlights poor long term outcomes, finding that a majority of individuals successful at WL regain a third of lost body weight within the first year following WL treatment and fully regain back to baseline body weight within 3-5 years [11-13]. This suggests that current behavioral methods implemented among clinical trials may not be effective in the long term.

However, the field has not yet adopted a universal definition of successful WTLM, and consequently, research studies use different criteria to define WTLM, impacting the ability to review WTLM literature in a methodological manner [7]. In 2001, Wing and Hill suggested that WTLM should be defined as intentionally losing ≥10% body weight and maintaining that WL for ≥1 year [14], and based on this definition, a review by Wing and Phelan [15] determined only 20% of individuals enrolled in behavioral-based clinical trials are successful at WTLM. Both those successful at WTLM and those who regain weight after WL experience similar situations and potential barriers to WTLM; however, it appears that the responses of individuals to these barriers are what lead some individuals to success but not others [16]. As Rena Wing noted, "A key question we need to address is what makes maintenance so difficult: is it physiology or psychology or some combination?" [17]. Asked another way, can we identify specific predictors of WTLM success and failure?

Successful Behaviors in WTLM

The National Weight Control Registry (NWCR), an ongoing database of individuals successful at WTLM, has attempted to characterize individuals successful at WTLM in order to distinguish methods, approaches, and attributes necessary for WL and WTLM. For inclusion in the study, participants are required to have lost 30 lbs (13.6 kg) and maintained that WL for \geq 1 year, as assessed by self-reported data [14]. By and large, NWCR participants greatly exceed these requirements, with an average of about 72 lbs of weight lost upon registration and maintenance of \geq 30 lbs lost body weight for an average of 5.7 years [15]. Since its inception in 1994, the NWCR has gained over 5,000 members [18] and serves as a foundation for many randomized controlled trial designs and WTLM recommendations. Interestingly, NWCR

members have reported a variety of methods for achieving WL goals but strikingly similar approaches to WTLM [19]. Within these similar approaches, individuals exhibit behaviors in varying amounts and in different combinations, seemingly choosing behaviors that best fit their lifestyles to reach their goals [10, 15]. To maintain WL, NWCR participants consume low calorie and low fat diets [20], engage in high levels of physical activity [20, 21], frequently self-monitor weight [20, 22], consume breakfast daily [23], and proactively catch weight relapses before large weight regains occur [15, 22]; these hallmark approaches are exhibited consistently in non-NWCR studies as well [16]. The decline in these behaviors among those who regain weight suggests that they play a key role in successful WTLM [15]. Additionally, the likelihood of long-term success increases as the number of behavioral changes increases [24]; long-term WTLM is better sustained in individuals making ≥5 behavioral changes than those making fewer changes, suggesting that a combination of behaviors is most suitable for WTLM success [7].

Despite using similar behaviors to achieve WTLM, perceived challenges differ among those successful at WTLM, with those who lost weight on their own reporting the least difficulty in WTLM compared to those in an organized program or on a liquid diet [19], or on a commercial diet or very low calorie diet [25]. Furthermore, a recent cluster analysis of the NWCR indicates that nearly 50% of the sample achieves WTLM by "non-typical" means (e.g., engaging in low amounts of physical activity, continuing to struggle with weight cycling and lapses, maintaining rigid control of food choices, etc.) [18]. This evidence implicates the need for autonomy or selection of techniques that are appropriate for individuals in clinical and commercial WL and WTLM programs, rather than prescribing generic WL and WTLM treatments. Though key behaviors are still present among those successful at WTLM, individual characteristics and lifestyle factors may dictate the specific components of a treatment that are most effective for each individual.

Predictors of WTLM

Because a universal treatment plan for WTLM does not always yield successful results [18], researchers have attempted to identify predictors (i.e., mediators and moderators) of successful WTLM with the intent of developing flexible WTLM treatments that can be altered based on an individual's preferences, behaviors, and lifestyle. Mediators are factors that can be altered by treatment and determine why a treatment is effective in eliciting the desired outcome,

and moderators are preceding characteristics and factors that determine for whom and under what conditions an intervention is effective [7]. As Teixeira *et al.* [26] stressed, the success of a WL program likely depends on the interaction between both characteristics of the individual and characteristics of the treatment. This observation could easily be extended to include WTLM programs. Identifying specific mediators and moderators of successful WTLM would allow individuals and treatments to be matched and, thus, enhance WTLM success [7]. Rather than attempting to conform an individual to a specific WTLM treatment, WTLM treatments should be developed to fit within an individual's needs, based on these potential mediators and moderators [7, 10, 26].

Sex Differences in WTLM

One often overlooked moderator in potentially predicting WTLM success is sex. A long-standing notion that men are more successful at WL and WTLM with less effort than women exists among the general public as well as practitioners [27]; however, research comparing sex differences in WTLM is sparse [28, 29]. Men are typically underrepresented in behavioral interventions [29], and rather than reporting outcomes by sex, data is statistically adjusted for sex [28]. The low participation rate of men in WL and WTLM studies may be because men choose to lose weight on their own, as opposed to utilizing an organized program, more often than women [25]. Among the NWCR, only 6% of participants who used an organized program for WL were men, but 27% of those who lost weight on their own were men [30]. In terms of addressing predictors of WTLM, this conventionality of statistical adjustment leaves a critical gap in WTLM research.

Through structural equation modeling, Wang *et al.* [31] found that men and women have a similar mediator (i.e., attention to weight and health habits) in predicting eating behavior, eating out behavior, and physical activity (i.e., health behavior outcomes) but very different moderators that affect attention to weight and health habits, including demographics, lifestyle factors, and psychological variables [31]. In fact, they discovered that the predominant difference between sexes was the complexity and interdependence of predictors on health behavior outcomes in the model for women compared to the much simpler model for men. Recent research has suggested that failed attempts at WL and WTLM are largely a result of an interaction of biological and environmental factors that influence behaviors, rather than simply

behavioral choices alone [32]. While weight gain may be a simple equation of greater energy intake than energy output, genetic sensitivities to neurobiological responses (e.g., sensation of pleasure from food reward through dopaminergic pathways) caused by environmental factors (e.g., greater availability of and access to palatable foods) may make behavioral choices supporting WL and WTLM more difficult for some people [32]. Rather than viewing behaviors as stand-alone antecedents to WL and WTLM success, clinicians and WTLM treatments should acknowledge the biological processes that interact with environmental stimuli to shape behavioral choices [32], which can differ greatly between men and women.

In particular, sex hormones impact lipolysis and body fat deposition differently in men and women during different stages of life [28]. In premenopausal women, estrogen facilitates gluteo-femoral adipose deposition and lean body mass accretion [28] Additionally, fluctuations in estrogens and progesterone throughout the menstrual cycle alter acute energy intake, energy expenditure, and preferences for sweet and fatty foods [33, 34]; though long-term energy balance is typically maintained despite these fluctuations [28], WL and subsequent WTLM may be more difficult to attain. Weight gain during pregnancy and the development of gestational diabetes increase the likelihood of weight gain and obesity later in life [28, 33, 34]. Weight gain and an increase in abdominal adiposity are associated with the onset of menopause, presumably related to the sudden decline in estrogen concentrations [35]. Interestingly, after menopause WL efforts result in less abdominal body fat loss than in premenopausal women, suggesting the importance of estrogen in body fat distribution [28]. In men, however, the only sex hormonal change found to contribute to increased body fat accumulation is the decline in androgen concentrations that occur gradually over time [28].

In addition to reproductive hormonal differences affecting weight gain across the lifespan, women may not regulate energy intake as effectively as men. Men with higher energy expenditure through physical activity have lower body fat percentages than less active men, but this comparison is not found among women (r=-0.34, p<0.03 in men vs. r=0.27, p>0.05 in women) [36]. Additionally endurance training [37] and aerobic exercise at moderate intensity (55-70% VO₂max) [38] result in less body composition change in women than in men. This is likely due to sex differences in physiological response to exercise as well as increased compensatory energy intake in women but not in men. Research in exercise stimulation of energy intake-regulating hormones (i.e., insulin, leptin, and ghrelin) suggests that these hormone

concentrations shift more dramatically in women than in men to stimulate food intake in response to exercise [39]. This orexigenic response is seen in an acute energy deficit state immediately following exercise and persists even after restoration of energy balance (achieved by a post-exercise *ad libitum* meal) [39]. In measuring sex differences in acute energy intake compensation, Davy *et al.* [40] found that men were able to more accurately regulate energy intake during an *ad libitum* meal after consuming a calorie-containing preload than women (86±5% vs. 74±5% compensation for men and women, respectively, p=0.04) [40]. These data suggest that whether in a state of exercise-induced energy deficiency or in acute surplus of energy, physiologically, women may not regulate energy balance as well as men for the intention of WL and subsequent WTLM.

There is a need for inexpensive, practical solutions for effective WTLM that can be implemented at the clinical level [6, 16]. Over the last decade, WTLM research has shifted focus from WTLM treatment study designs to the identification of potential interactions of treatment characteristics and characteristics of individuals leading to WTLM success. From this research, specific behaviors and other notable factors have been identified as predictors of WTLM success, but the potential moderator of sex has not been evaluated. Research comparing sex differences in weight change outcomes and behaviors related to weight change would prove invaluable in the quest to match individuals to effective WTLM treatments.

CHAPTER 2: Sex Differences in Behavioral Predictors of Successful Weight Loss Maintenance

I. Introduction

Approximately 47% of men and 75% of women diet for the purpose of WL at some time during their lives [9]; however, maintaining WL is challenging for most people, and relapse is common. A majority of those successful at WL regain all lost weight within 3-5 years after treatment [11-13], but for those who are able to maintain their initial WL for ≥2 years, the likelihood of continued success increases [30, 41]. In other words, the best predictor of continued WTLM success is the length of time of prior success. Therefore, determining effective methods to initiate WTLM could promote continued and sustainable success.

Changing lifestyle behaviors remains at the forefront of effective WTLM treatment strategies. Self-monitoring of body weight, physical activity, and fruit and vegetable consumption are effective WTLM behaviors [19, 22], and increasing water intake may be an important strategy as well [42, 43]. However, recent research suggests individuals successful at WTLM implement behavior changes in varying amounts and combinations based on personal preferences and needs. A recent cluster analysis of participants in the NWCR found that among current participants, nearly 50% achieve WTLM using non-typical strategies and behaviors [18]. For example, despite evidence that WTLM is improved with >2,000 kcal/week energy expenditure through physical activity [44], approximately 10% of this sample achieved WTLM by expending about 728 kcal/week through physical activity (vs. 2,853 kcal/week in "typical" NWCR participants) [18].

It is widely recognized that weight change in response to habitual physical activity and dietary intake exhibits a wide inter-individual variability, and thus, despite similar amounts of physical activity or patterns of dietary intake, some individuals may not achieve successful WTLM [45]. This individual variability in behavior implementation and weight change responses [45], has led researchers to attempt to identify specific predictors of successful WTLM in order to develop more effective WTLM strategies. Behavioral and physiological evidence suggest that sex may be an important predictor of success, but due to underrepresentation of men among WTLM studies, it is often overlooked. Some evidence suggests that women experience a compensatory increase in energy intake in response to physical activity, which may thwart

efforts to maintain WL through physical activity, whereas men do not [39, 46]. Other research indicates that men more accurately regulate energy intake in an acute *ad libitum* meal after a calorie-containing preload [40]. Because many behavioral processes are influenced by physiological functions [32], it is likely that men and women approach WTLM with differing behaviors.

Within this context, this investigation had several aims. The first aim was to determine if there was a sex difference in maintenance of clinically significant WL. A second aim was to determine if there were differences in the interaction of sex and WTLM behaviors, specifically in fruit and vegetable intake and physical activity. Lastly, an exploratory aim was to observe occurrences of weight relapse (i.e., ≥ 3 lb weight gain) and describe behavior changes in relation to weight change.

II. Materials and Methods

Protocol

The study designs of both the WL and WTLM trials have been described previously [47, 48]. Briefly, the purpose of the WL trial was to determine if a water preload prior to meals facilitates greater WL than a hypocaloric diet alone in middle-aged and older adults [47]. Following the WL trial, the same participants were invited to participate in the WTLM trial, regardless of the amount of weight lost [48]. The purpose of the WTLM trial was to determine the effectiveness of a WTLM intervention utilizing behavioral techniques known to facilitate WTLM [48]. Thirty-nine weight-reduced individuals who completed the 12-week WL trial also completed the 12-month WTLM trial. Individuals continued within their WL trial randomization group (i.e., 500 ml water preload only or no water preload) but without caloric restriction and were asked to self-monitor their daily body weight, physical activity (measured by pedometer step count), and fruit and vegetable intake (measured by servings). Participants in the water preload group were asked to additionally self-monitor their water consumption [48]. All participants were provided tracking sheets to record their daily behaviors and were asked to return tracking sheets weekly to study personnel [48]. Overall program goals for all participants were to maintain their reduced body weight (within 3 lbs of their laboratory-measured baseline body weight), achieve 10,000 or more steps per day, consume at least 5 servings of fruits and vegetables daily, and, for the water preload group only, consume at least 48 fl oz of water each

day [48]. Participants were considered compliant with returning tracking sheets regardless of accuracy or completeness, and they were given credit for adherence to each self-monitoring behavior regardless of accuracy in data recorded. Additionally, monthly laboratory assessments of body weight, 4-day food intake records, resting blood pressure, and counseling sessions with a registered dietitian were conducted [48]. Additional laboratory assessments of height, waist circumference, body composition (DXA) (GE Lunar Prodigy; GE Healthcare, Madison, WI), resting metabolic rate (RMR) via indirect calorimetry (Parvo Medics TruOne 2400, Sandy, UT), health beliefs survey, and 24-hr urine collection (total volume and specific gravity) (Fisher UriSystem; Fisher Scientific, Hampton, NH) were conducted at baseline, 6, and 12 months [48]. For the purposes of this *post hoc* analysis, groups were distinguished by sex, rather than the original randomization to water preload or no water preload groups, and successful WTLM was defined as remaining below or within 3 lbs of baseline-measured body weight.

Statistical Methods

Statistical analyses were performed with the Statistical Package for Social Sciences software (SPSS, version 20.0 for Windows, 2011, SPSS Inc, Chicago, IL). Baseline characteristics for men and women were assessed using independent samples *t*-tests and descriptive statistics.

Clinically Significant WL

Sex difference in clinical significance of overall WL at 12 months of the WTLM trial was analyzed with Pearson's X^2 test, using the criterion of \geq 5% total WL, from baseline of the WL trial. A 5-10% WL in obese patients is associated with reductions in mortality and risk factors for cardiovascular disease and type 2 diabetes [8], and therefore, maintenance of even modest WL would provide important health benefits for most reduced-obese individuals.

<u>Interaction of Sex and WTLM Behaviors</u>

To assess potential interactions of sex and behavioral predictors of WTLM, a random coefficients (mixed) model (i.e., growth curve analysis) was used because it is able to correct for measurement unreliability and uses individual trajectories to measure change rather than averages [49]. Due to the high variance in reported physical activity, log-transformed physical

activity was used in the model. Potential physiological predictors, including resting metabolic rate per kg of fat free mass (RMR per kg FFM) and percent body fat measured at baseline, 6, and 12 months, were not included in the growth curve model because no sex differences were found in these variables during preliminary analyses. Additionally, due to the small sample size, the growth curve model was bootstrapped using 1,000 samples with the 0-6 month and 7-11 month time frames.

Qualitative Analysis of Weight Relapse

SPSS and Microsoft Excel software (Microsoft Corporation, version 12.0, 2007, Redmond, WA) were used in a qualitative assessment of behavior changes and their associations with relapse (i.e., weight regain). Relapse was defined as >3 lb weight regain. Single missing values for daily body weights were replaced using the mean of nearby points in SPSS, and missing daily values for behaviors (physical activity, fruit and vegetable intake, and water consumption) were imputed using the expectation-maximization algorithm in the Missing Value Analysis module of SPSS. Expectation-maximization estimation for missing values relies on the assumption that data are missing at random (MAR) [50]. The expectation-maximization method first determines a conditional expectation for a missing value based on observed values and then uses maximum likelihood estimates of parameters to find the most likely value [50]. Because of the high daily variability of behavioral data, in contrast to the relatively consistent daily body weight measurements, the expectation-maximization algorithm was used rather than calculating the mean of surrounding data points. Once missing values were replaced, Microsoft Excel was used to calculate weekly averages of body weight, exercise, fruit and vegetable intake, and water consumption (for the water preload group only). Individual line graphs illustrating the changes in weekly averages of these variables were created for each participant.

The individual graphs were then divided into categories based on end weight outcomes, either successful or unsuccessful in terms of a 3 lb regain. Participants were then characterized using the following 4 discrete and mutually exclusive weight change categories: WL (n=13), weight stable (n=7), relapse with recovery (n=9), and relapse without recovery (n=10). WL participants were defined as those who lost weight over the course of the 12-month period, and their average final week remained ≥3 lbs below baseline weight. Weight stable participants remained within 3 lbs of baseline weight and never exceeded a 3 lb gain from baseline. Those in

the relapse with recovery group gained ≥ 3 lbs more than baseline body weight at least once during the study period but recovered to within 3 lbs of baseline weight by the final week's average weight. The relapse without recovery group consisted of individuals who gained ≥ 3 lbs more than baseline weight at least once during the study period and remained ≥ 3 lbs above baseline weight during the final week.

Once graphs were categorized, three researchers then independently reviewed individual graphs within each category and discussed observations. The researchers agreed that individuals who were noncompliant in returning tracking sheets for weeks 45-52 consecutively would be excluded from analysis (n=10) based on the reasoning that their imputed average weights and behaviors for the final weeks may not be actual and could potentially categorize an individual incorrectly. Because our aim was to characterize the adoption of specific behaviors related to body weight outcomes (i.e., predictors), this exclusion is justified. After this exclusion, individual characteristics related to weight change and behavior change were assessed and observations were discussed among researchers.

Based on these general observations, the researchers determined that a crisp set qualitative comparative analysis (QCA) was appropriate for analysis to determine behavioral conditions and factors required for the desired outcome (i.e., successful WTLM) to occur. QCA is a beneficial tool in exploratory evaluation to probe for potential preliminary information with combined qualitative and quantitative techniques [51]. In this type of analysis, conditions potentially associated with a given outcome are calibrated in a dichotomous manner to identify multiple causations of an outcome while still maintaining the heterogeneity of individual characteristics [51]. Conditions deemed "necessary" are present in all successful categories but may also be present in unsuccessful ones, and "sufficient" conditions or combinations of conditions are present only in successful categories and must be present for the desired outcome to occur [51]. For the QCA, researchers determined a list of potentially causal conditions, and decision rules were defined for each condition. Data was then dichotomously calibrated for each condition based on the specifically defined rules, and results were documented in a truth table. Additionally, causal conditions were assessed for men and women separately to allow a comparison of sex differences.

III. Results

Baseline participant characteristics are shown in Table 1. Over 42% of participants were male, and there were no significant differences in any characteristic between men and women.

Clinically Significant WL

There was no significant sex difference in achieving clinically significant WL (\geq 5% WL) at 12 months (X^2 =0.123, p=0.726).

Interaction of Sex and WTLM Behaviors

Figures 1a depicts the growth curve model, and Figures 1b and 1c highlight the growth curve model bootstrapped with 0-6 months and 7-11 months, respectively. In the overall growth curve model, the sex difference in weight change was not statistically significant (p=0.852). Visual inspection of the growth curve model indicates potential differences in weight change between men and women during months 1, 4-6, and 10-12 may be present; however, bootstrapping with the two time frames did not find statistically significant differences for any time point. It is likely that there was not enough power to detect statistically significant differences in these changes.

Qualitative Analysis

Table 2 presents the raw data of the truth table results as WTLM outcome groups. The truth table revealed 4 conditions considered necessary for successful WTLM overall: (1) adherence to ≥ 1 behavioral goal, (2) adherence to the fruit and vegetable intake goal, (3) adherence to the water intake goal, and (4) occurrence of weight gain during the holidays. No 2 groups shared the same pattern of conditions overall. Interestingly, the condition of early first relapse was found to be a necessary and sufficient condition for failure of WTLM. In other words, if an individual gained ≥ 3 lbs during the first 13 weeks of the intervention, he or she was guaranteed to fail at WTLM. Overall, continued WL at 12 weeks and a maximum WL of ≥ 5 lbs from WTLM baseline body weight as a combination of conditions were sufficient for the WL outcome at 12 months.

Table 3 illustrates the truth table with groups divided by sex and highlights important observations of sex differences. When interpreting this data, however, it is important to keep in

mind the small sample size. Interestingly, only for men in the WL group was weight gain during the holidays not a necessary condition; for all other sex and outcome group categories, weight gain during the holidays was present. Men in both the relapse with recovery and relapse without recovery groups were adherent to ≥ 2 behavioral goals, but this condition was not present in any outcome group for women. For men that experienced an early first relapse, the additional condition of ≥ 5 lb maximum WL from baseline weight was sufficient for recovering from relapse.

Figures 2, 3, 4, and 5 are examples of the individual graphs used to generate the truth tables and are representative of the truth table results. In general, participants categorized in the WL group were adherent to the fruit and vegetable intake goal but did not exceed the goal on average throughout the study. Additionally, they continued to lose weight through the first 3 months and achieved ≥ 5 lb weight loss overall (measured from baseline body weight), as illustrated in Figure 2. Weight stable individuals exceeded at least 1 behavioral goal, either the fruit and vegetable intake goal or the water goal, and experienced weight gain during the holidays. While some may have lost weight throughout the study period, particularly during the first 3 months, the group as a whole never lost ≥5 lbs. This characterization is shown in Figure 3. In Figure 4, the relapse with recovery group example illustrates that ≥ 1 behavioral goal was exceeded. While this figure demonstrates adherence to the fruit and vegetable goal and exceeding the water intake goal among women in the group, men in the group may have also exceeded the physical activity goal. The individual in the relapse without recovery group (Figure 5) highlights an early first relapse as well as an increased weight during the holiday period. Additionally, adherence to ≥ 1 behavioral goal was exhibited; in this case, the fruit and vegetable goal was exceeded, as is characteristic of men in the group.

IV. Discussion

This analysis possesses several unique strengths. First, it utilized individuals who were highly successful overall at WTLM (i.e., 80% success rate at 12 months) when compared to similar clinical WTLM interventions across the field. Wing and Phelan [15] noted an approximately 20% success rate at WTLM across studies, when success is defined as maintaining \geq 10% WL for \geq 1 year. Second, the WL trial produced similar relative WL results in men and women (-7.78 \pm 0.82% and -7.05 \pm 0.78%, respectively); thus, both men and women

began the WTLM trial with nearly the same reductions in body weight. Third, about 43% of the WTLM sample was comprised of men, a proportion much higher than found in most behavioral interventions, and therefore, comparisons between sexes could be made. Fourth, 12 months of daily self-reported body weight, physical activity, fruit and vegetable intake, and water intake for each individual were available for exploratory analysis of the inter-individual variability in behavior change surrounding weight change.

Overall, no significant sex difference in weight change over time was found, but as noted previously, visual inspection of the growth curve model suggests a similar study with appropriate power may find significant sex differences in weight change over time or interactions of sex and behavioral predictors. Future research should examine sex differences as a primary outcome, rather than a *post hoc* analysis as this investigation did, and conduct *a priori* power analyses to ensure appropriate power. Additionally, future randomized controlled trials should target recruitment of more men to achieve more balanced and representative sample of individuals attempting WTLM. Furthermore, because men are more likely to engage in WL and WTLM on their own rather than through a structured program, more qualitative research may be able to determine specific aspects of WTLM treatments that men find appealing and helpful in their efforts. This would aid in the development of appropriate individualized treatment strategies.

The QCA found that holiday weight gain is inherent for most all individuals attempting WTLM, and previous research has also acknowledged such findings [52]. In this analysis relapse occurred during the holidays for some individuals, but for others it did not; only for men in the WL group was the condition of weight gain during the holidays not found to be necessary. Other research also suggests that there may be a high individual variability in holiday weight gain, particularly among those who have recently lost weight [53]. Thus, some amount of weight gain during the holiday period is likely; however, holiday weight gain likely does not affect WTLM outcomes nor relate to irrecoverable relapse.

Oddly, adherence to the physical activity goal was not found to be a sufficient or necessary condition for WTLM success; this finding is in contrast to extensive data acknowledging physical activity as a principal behavior among individuals successful at WTLM and a potential predictor of success [20, 21, 54, 55]. In fact, only men in the relapse with recovery group exceeded the physical activity goal. It may be that individuals did increase engagement in physical activity compared to baseline amounts, but they may not have been able

to meet the 10,000 steps/day goal set by the study investigators and, thus, were considered non-adherent.

The results of the QCA indicate that the key to WTLM success was in the first 3 months of the intervention. Those who were successful, despite relapse even, continued to lose weight until at least 12 weeks of treatment. This may have allowed them to create a weight "buffer" to prevent excessive and irrecoverable weight gain. In contrast, individuals who failed at overall WTLM, despite efforts to recover (i.e., increasing engagement in behaviors), experienced relapse early in the intervention (within approximately 3 months). These findings are in agreement with a study of the NWCR, which found that few participants recover from even small (1-2 kg) amounts of weight regain and that preventing large regains from occurring early during WTLM is vital to recovering from relapses that occur later in WTLM [15]. From these findings, it appears that WTLM success at 12-months may be dictated by the patterns of weight change early during WTLM; therefore, the initial weeks of WTLM treatment are likely a "high-risk" period that requires more vigilant efforts in behavior modification to ensure future success.

Furthermore, the WL outcome group was the largest (n=10), suggesting that perhaps personal WL goals had not yet been achieved at the conclusion of the 12-week WL trial. These findings lend further support to other research concluding that maximum WL is typically achieved by approximately 6 months of treatment [56]. Additionally, individuals who lose more weight early on during WL treatment have been found to sustain WTLM success longer than those who gradually lose weight more gradually [56]. Thus, more intensive WL treatments lasting at least 6 months to maximize WL coupled with vigilant weight and behavior monitoring during the transition from WL to WTLM may enhance long-term WTLM success.

There are several limitations within this analysis. Predominantly, the high prevalence of missing data made statistical and qualitative analyses difficult to conduct, as continuous weeks of missing data could be interpreted as either a decline in self-monitoring of behaviors or simply as noncompliance with the treatment protocol. Second, the duration of the study may not effectively measure long-term WTLM. Long-term WTLM is best observed in studies with 18-30 months of follow-up after treatment initiation, with a 5-year follow-up being ideal [56]. Therefore, this study may not have a long enough follow-up to fully evaluate the effectiveness of behaviors used in WTLM. Additionally, the representativeness of the sample is limited in that a majority of the sample is white, and therefore, may not be indicative of all individuals attempting

WTLM. However, this offers some benefit as it more closely matches samples of similar studies (including the NWCR) to allow for comparisons. The appropriateness of self-reported weight is questioned because women, overweight individuals, and people >45 years old are known to systematically underreport weight [57]. Among WTLM studies, however, self-reported weights and behaviors are regarded as acceptable measures. This study has overcome the inherent flaws of self-reporting to an extent because all participants were provided with the same model of body weight scale and pedometers to track physical activity. Additionally, self-monitored weights were highly correlated with monthly body weights measured in laboratory assessments (p=0.99). Self-monitoring was intentionally included in the study design as it is an effective behavioral approach to WTLM in and of itself [12, 22, 58]. Though this study was experimental by design, this analysis assessed the relationship between behavior change and weight change but cannot imply a causal relationship.

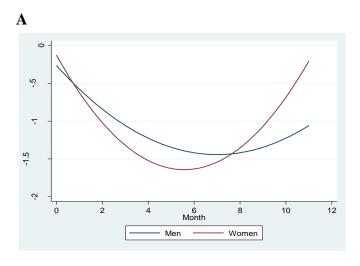
In summary, sex differences in weight change or total WL outcomes were not found in this analysis; however, evidence from this research indicates that men and women may approach WTLM with different behaviors. Further research to identify predictors of successful WTLM, particularly pretreatment factors (including sex), is essential to determine appropriate WTLM treatment strategies for an individualized approach. In current practice, intensive WL treatment lasting at least 6 months should be used to maximize initial WL, and concerted effort should be made during the transition period from WL to WTLM to vigilantly monitor weight the prevent large, early weight regains, which can sabotage future WTLM success. Additionally, WTLM treatment programs should implement the concept of individualized treatment in current practice, even though research has not determined all factors predicting success, and should focus on autonomy and flexibility in treatment strategies to match individuals' preferences with treatment characteristics.

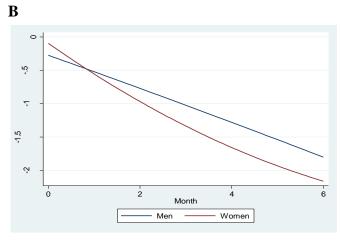
 Table 1. Results: Baseline characteristics of WTLM trial participants.

Characteristic	Men (n=17, 42.5%)	Women (n=23, 57.5%)
Age, yrs	62.9 ± 1.72	62.4 ± 1.02
Race/Ethnicity		
White, n	16	21
Nonwhite, n	1	2
BMI, kg/m ²	28.96 ± 0.97	29.56 ± 1.13
Mean Prior Weight Loss, kg (%)	$7.61 \pm 0.84 \ (-7.78 \pm 0.82)$	$6.00 \pm 0.75 \ (-7.05 \pm 0.78)$

Values shown are means \pm SEM or frequency counts.

Figure 1. Results: (A) Body weight change according to monthly laboratory body weight measurements among men and women, (B) Body weight change bootstrapped with 0-6 months among men and women, (C) Body weight change bootstrapped with 7-11 months among men and women.





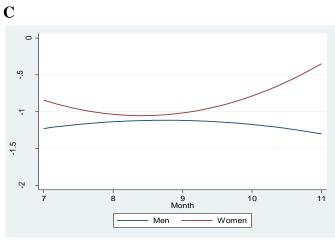


Table 2. Results: Fourteen conditions were dichotomously evaluated in a qualitative comparative analysis truth table to determine behavior change and predictors surrounding weight changes and outcomes.

	WL	Weight Stable	Relapse with Recovery	Relapse without Recovery
Adherence to ≥1 Goal	1	1	1	1
Adherence to FV Goal	1	1	1	1
Adherence to PA Goal	0	0	0	0
Adherence to Water Goal	1	1	1	1
Exceeded ≥ 1 Goal	0	1	1	1
Exceeded FV Goal	0	1	0	1
Exceeded PA Goal	0	0	0	0
Exceeded Water Goal	0	1	1	0
Continued WL through 12 Weeks	1	0	1	0
Weight Gain During Holidays	1	1	1	1
First Relapse During Holidays	0	0	0	0
Adherence to ≥ 2 Goals	0	0	1	0
Early First Relapse (≤13 Weeks)	0	0	0	1
≥ 5 lbs WL Maximum from Baseline Weight (at any point during 12-months)	1	0	0	0

Conditions present are designated by "1," and conditions not present are designated by "0".

Table 3. Results: Qualitative comparative analysis results comparing men and women within 4 WTLM outcome groups are presented as a truth table with a summary of key observations.

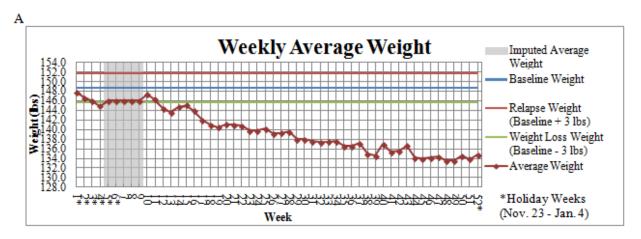
	WL		Weight Stable Relapse With Recovery		Wi	lapse thout covery	Observations		
	Men	Women	Men	Women	Men	Women	Men	Women	
	(n=4)	(n=6)	(n=2)	(n=4)	(n=1)	(n=6)	(n=3)	(n=3)	
Adherence to ≥1 Goal	1	1	1	1	1	1	1	1	Necessary condition for WTLM success in both sexes
Adherence to FV Goal	1	1	1	0	1	1	1	1	
Adherence to PA Goal	0	0	0	0	1	0	0	0	
Adherence to Water Goal	1	1	0	1	0	1	1	0	
Exceeded ≥ 1 Goal	0	0	1	1	1	1	1	0	
Exceeded FV Goal	0	0	1	0	1	0	1	0	
Exceeded PA Goal	0	0	0	0	1	0	0	0	
Exceeded Water Goal	0	0	0	1	0	1	0	0	
Continued WL through 12 Weeks	1	1	1	0	0	1	0	0	
Weight Gain During Holidays	0	1	1	1	1	1	1	1	Not a necessary condition only among men in the WL group
First Relapse During Holidays	0	0	0	0	1	0	0	0	
Adherence to ≥ 2 Behavior Goals	0	0	0	0	1	0	1	0	Only men were adherent to ≥2 behavior goals
Early First Relapse (≤13 Weeks)	0	0	0	0	1	0	1	1	Only subsection of men who experienced early relapse recovered from relapse
≥ 5 lbs WL Maximum from Baseline Weight (at any point during 12-months)	1	0	0	0	1	0	0	0	Necessary for WL Relapse with Recovery outcomes for men but not for women

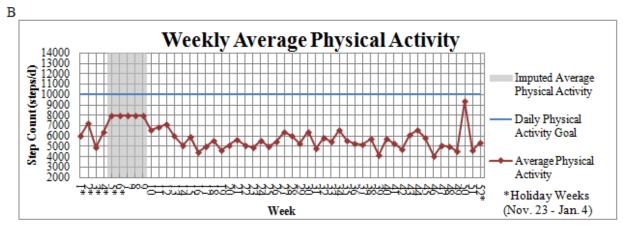
Conditions present are designated by "1," and conditions not present are designated by "0".

Figure 2. Results: Example of Weight Loss Group



Female





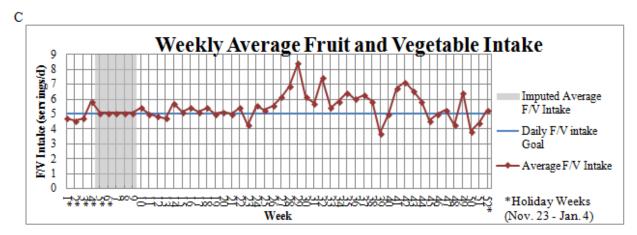
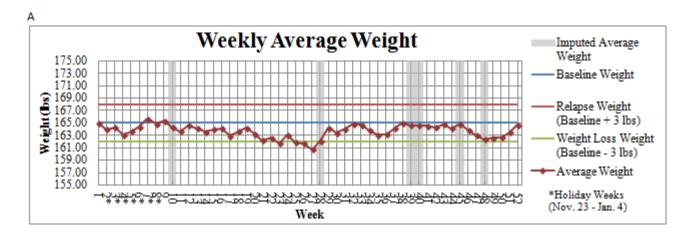
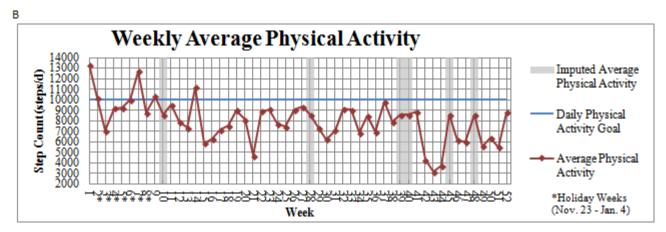


Figure 3. Results: Example of Weight Stable Group

PM71

Female





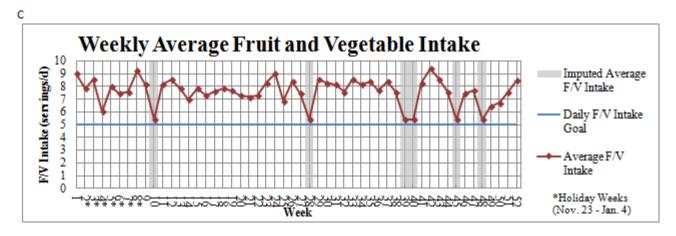
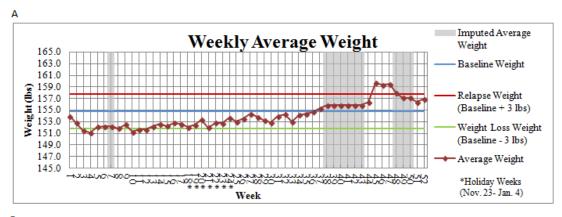
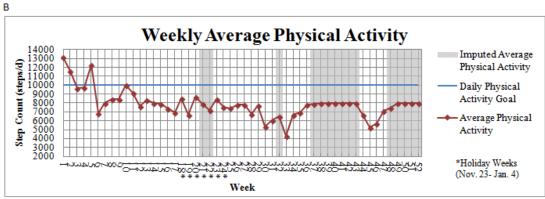


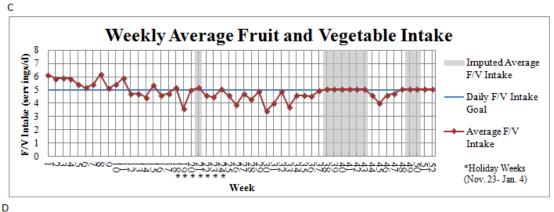
Figure 4. Results: Example of Relapse with Recovery Group

MB01

Female







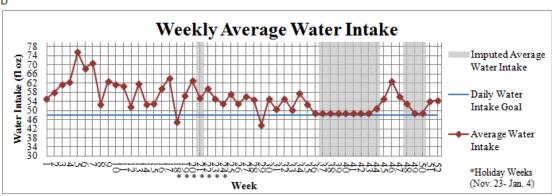
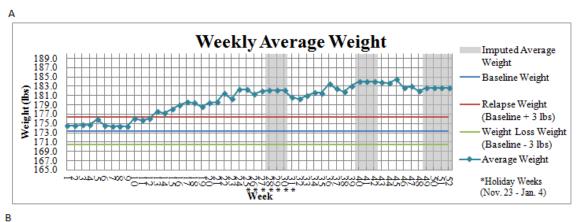
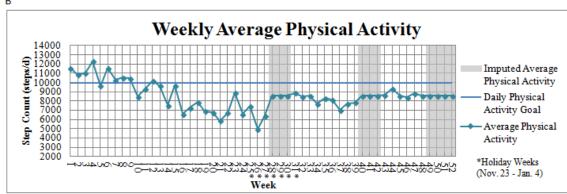
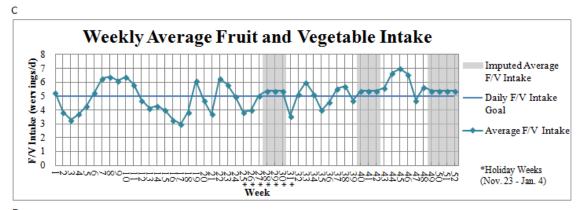


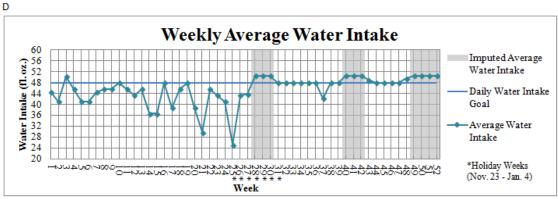
Figure 5. Results: Example of Relapse without Recovery Group EM51











CHAPTER 3: Conclusions and Implications for Future Research

There are implications that developing successful WTLM strategies based on individual characteristics will have a profound impact on weight management. NWCR data suggest that WTLM gets easier over time and that the length of time of prior success is the best predictor of continued WTLM success, particularly for those able to maintain initial WL for ≥ 5 years [15, 30]. Indeed, participants who have maintained WL for longer periods of time report requiring fewer behavioral strategies, specifically self-monitoring, than those who are not as experienced in WTLM. This suggests that these behaviors become a habitual lifestyle elements rather than behavior changes that require conscious awareness and effort [17]. For the future, research should continue along the lines of the preceding exploratory investigation in characterizing individual patterns of behaviors and their predictive associations with weight change, particularly with regard to sex. Understanding these behavior patterns and the inter-individual variability will assist in predicting potential WTLM relapse and may offer individuals a chance to correct weight regain before it occurs. To enhance WTLM success for the present, WTLM treatment programs should focus on effectively transitioning individuals from a point of maximum WL to the point where WTLM habits and behaviors become almost "second nature". To do this, they may need to adopt flexible approach, allowing individuals to pick and choose behavioral strategies that fit their lifestyles and enhance their motivation to continue.

WTLM research and treatment should also focus on increasing length of follow-up. Currently, few studies assess WTLM beyond 12-18 months, and, therefore, the effectiveness of strategies for truly long-term WTLM (i.e. ≥5 years) is still relatively unknown. Because obesity and WTLM are viewed as chronic relapsing conditions, treatment should be geared toward continuous, long-term care, whether implemented as a clinical program or in an individual's own efforts. Ideally, the best treatment strategy for long-term WTLM would be an indefinite intervention with frequent follow-up contact with an interventionist who can offer constructive, tailored feedback [59]. However, the financial and labor cost of this type of continuous care makes this a very challenging solution to implement. A viable alternative may be in utilizing a similar methodology as face-to-face contact but through a different mode of delivery, namely over the Internet or through some other form of electronic interaction. WTLM intervention follow-up delivered over the Internet has produced mixed results in effectiveness; however, the

lack of standardized delivery techniques (i.e., chat rooms vs. non-interactive modules) may be the cause of such varied findings [59]. Utilizing an Internet-based intervention with program content delivered in a chat room setting produces similar outcomes as face-to-face contact [60], and telephonic follow-up with an interventionist following a clinical WL trial results in similar WTLM outcomes as face-to-face contact but at lower implementation costs [61]. Likely, the individualized treatment and tailored feedback provided by interventionists, even through electronic or telephonic delivery systems, make certain interventions more successful at sustaining WTLM than others [59]. Certainly, further research in intervention follow-up delivered through cost-effective technology is necessary.

In summary, the focus of current WTLM treatment should be on individual care that matches characteristics of an individual with treatment characteristics. Additionally, a prolonged WL treatment period (i.e., ≥6 months) followed by an intensive transition period from WL to WTLM and individually-tailored feedback during follow-up should be used until behaviors become habitual and self-monitoring is no longer needed. Future research should consider the cost-effectiveness of delivery methods and look to better characterize individual predictors of WTLM success and failure in order to develop more effective WTLM strategies for individuals.

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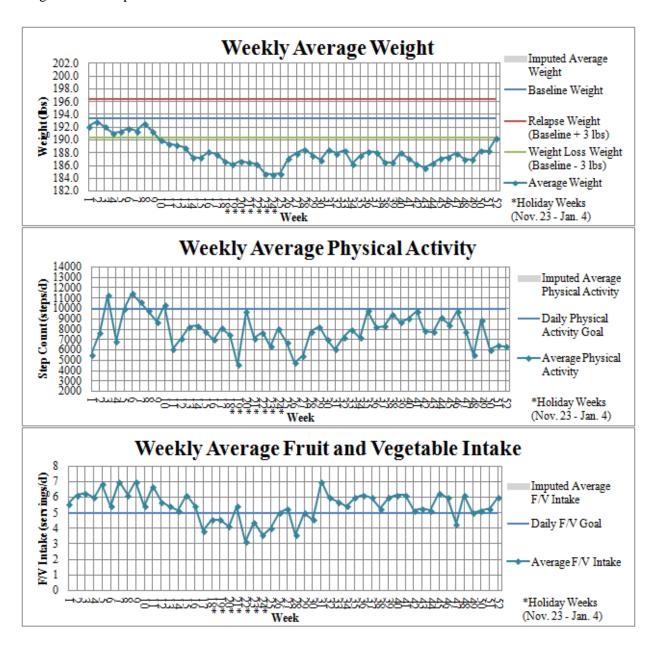
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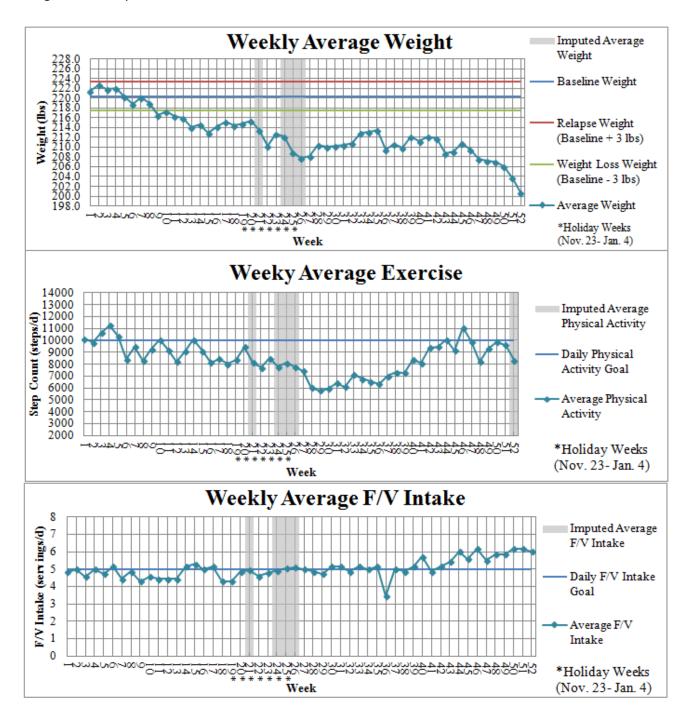
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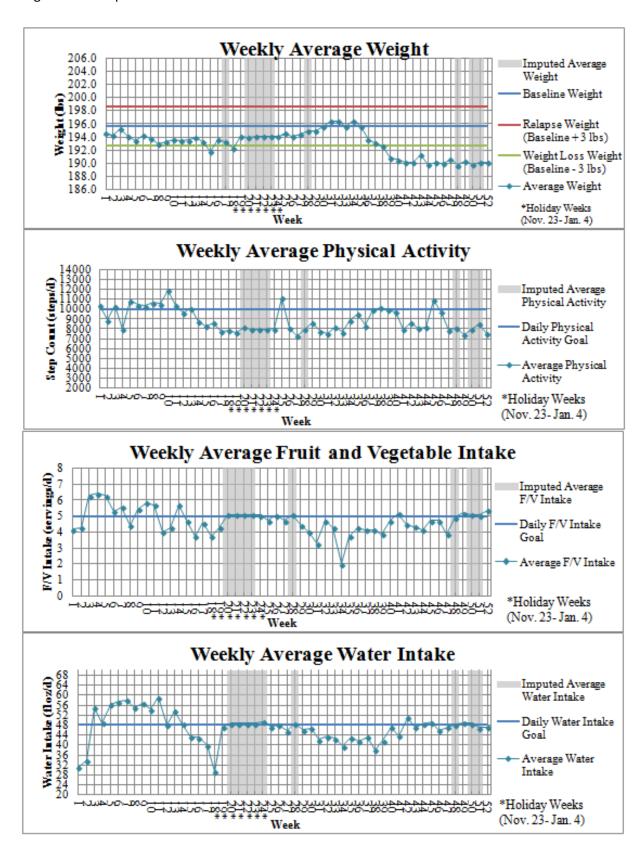
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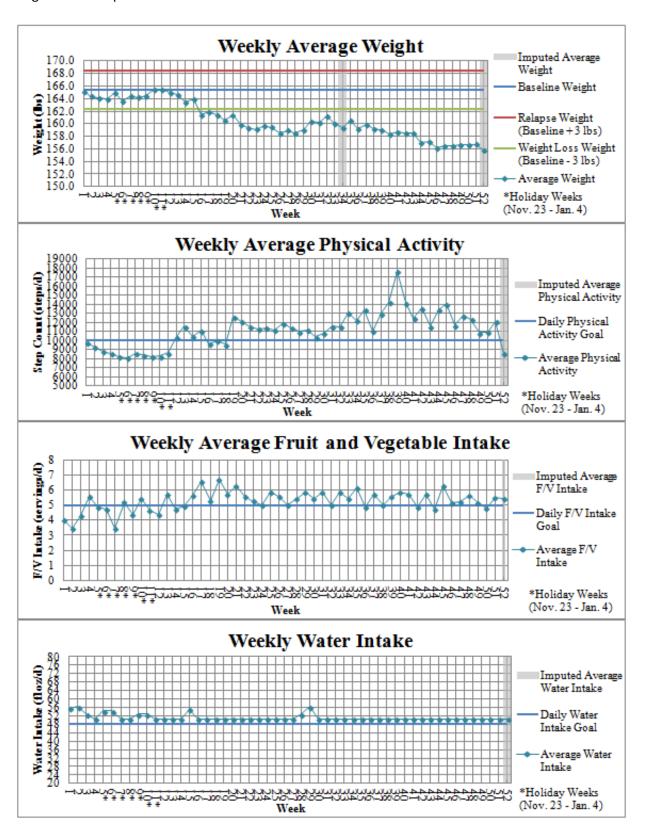
APPENDIX

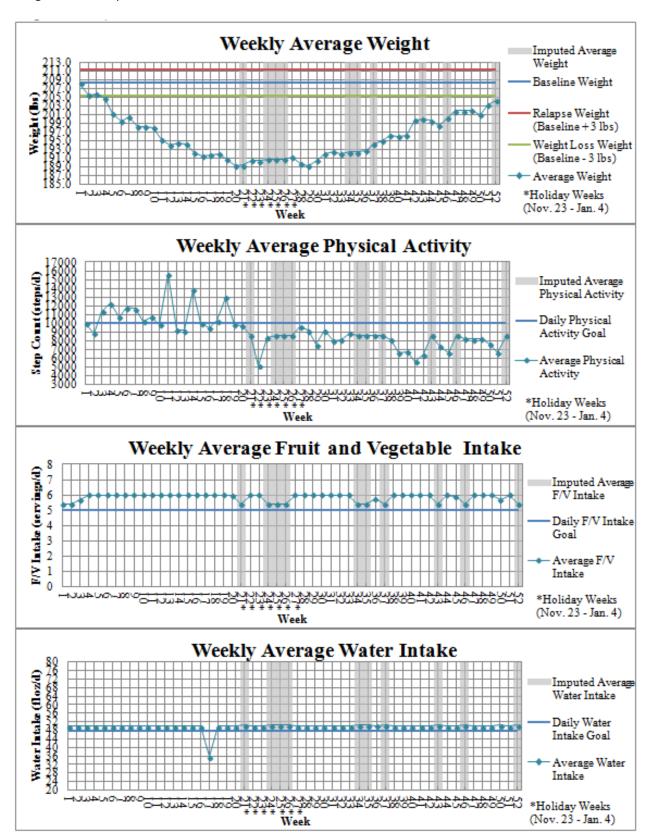
WL Group

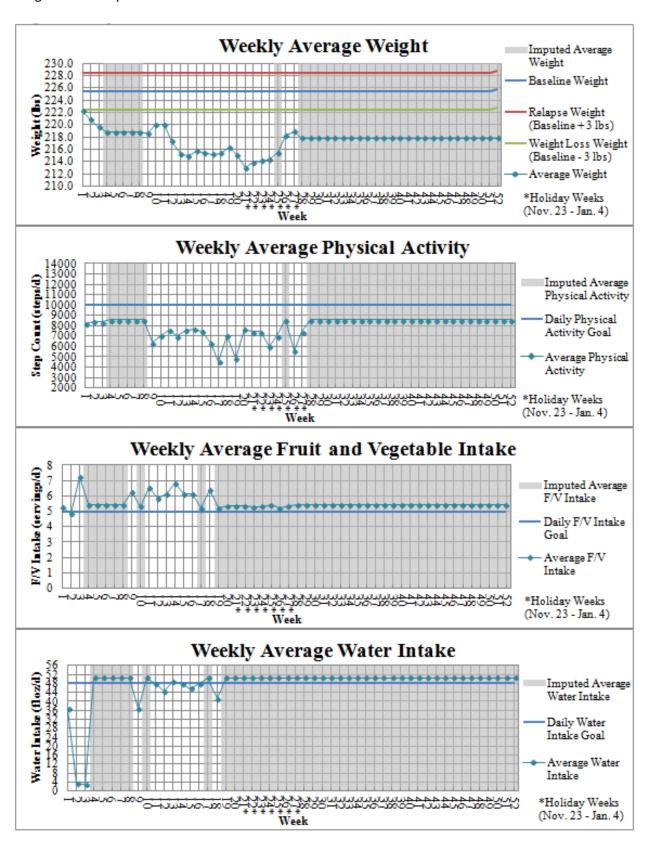


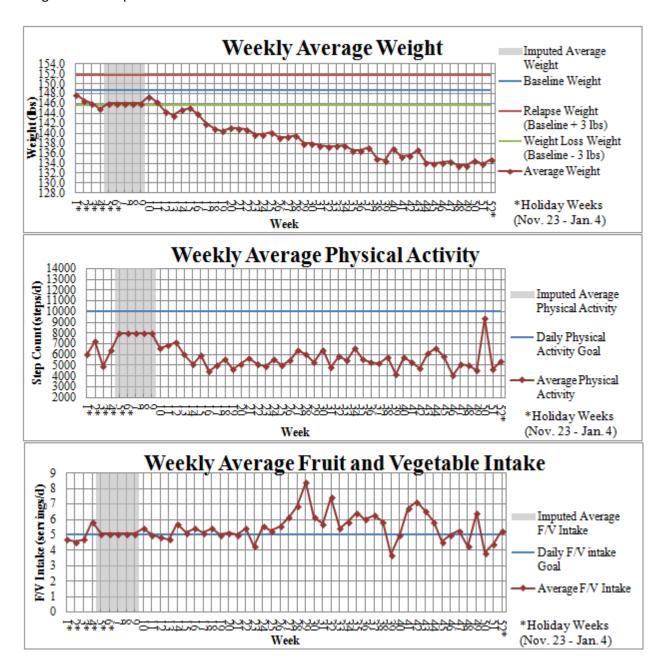


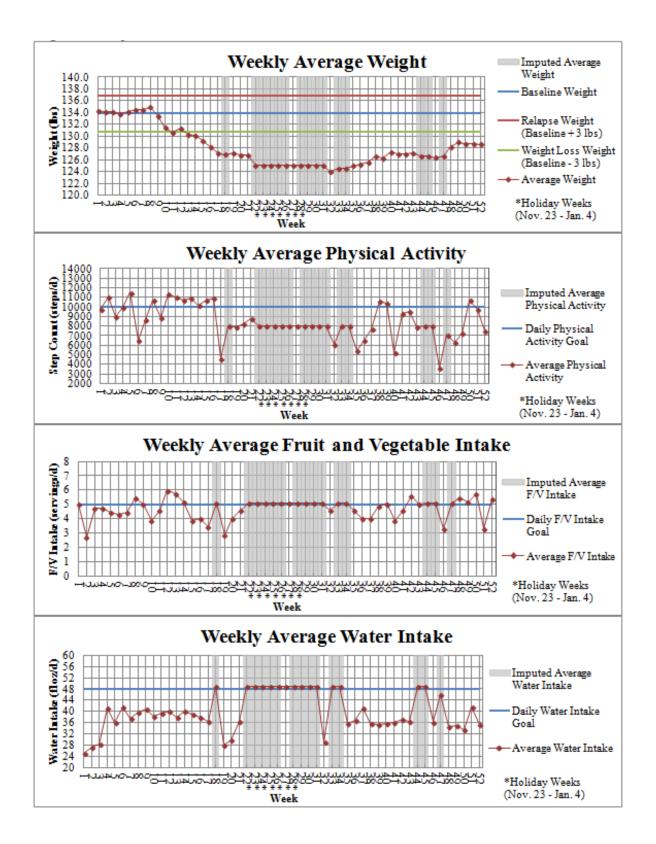


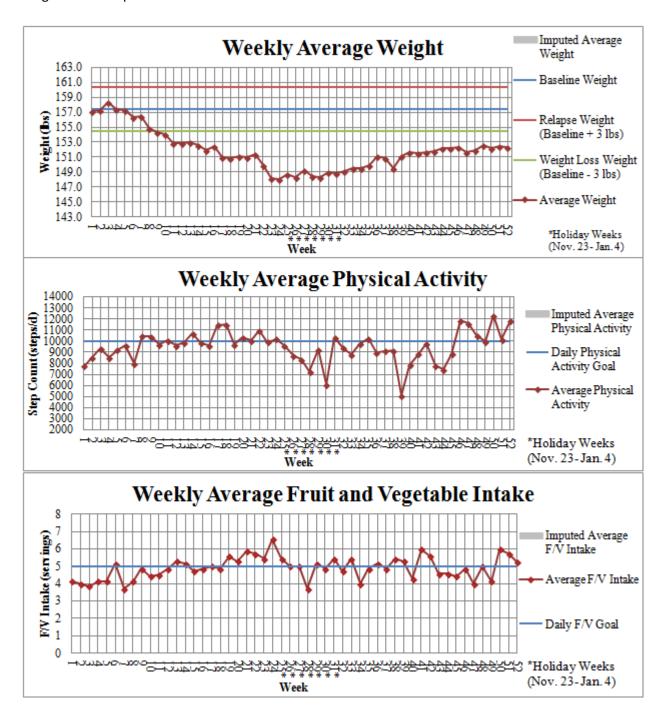


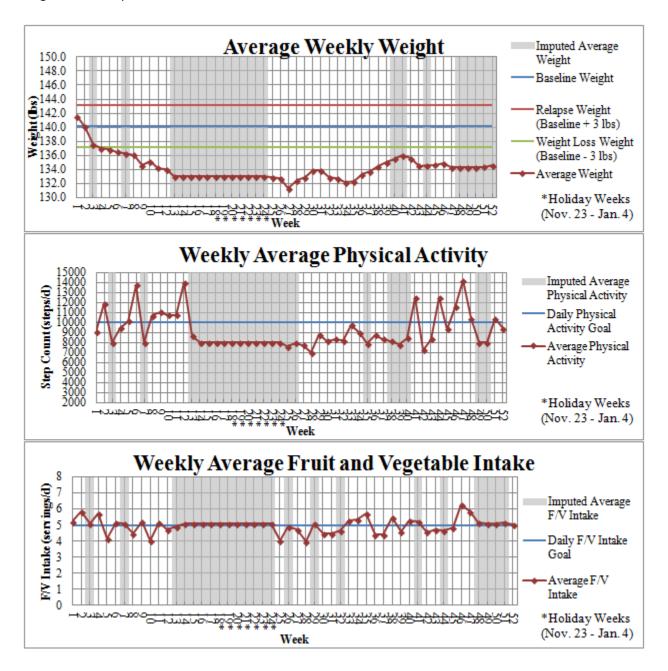


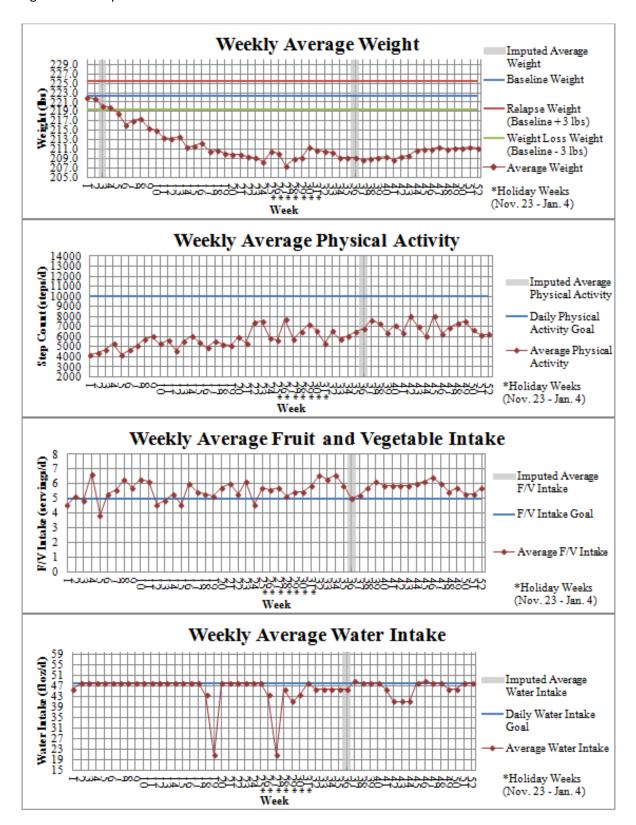


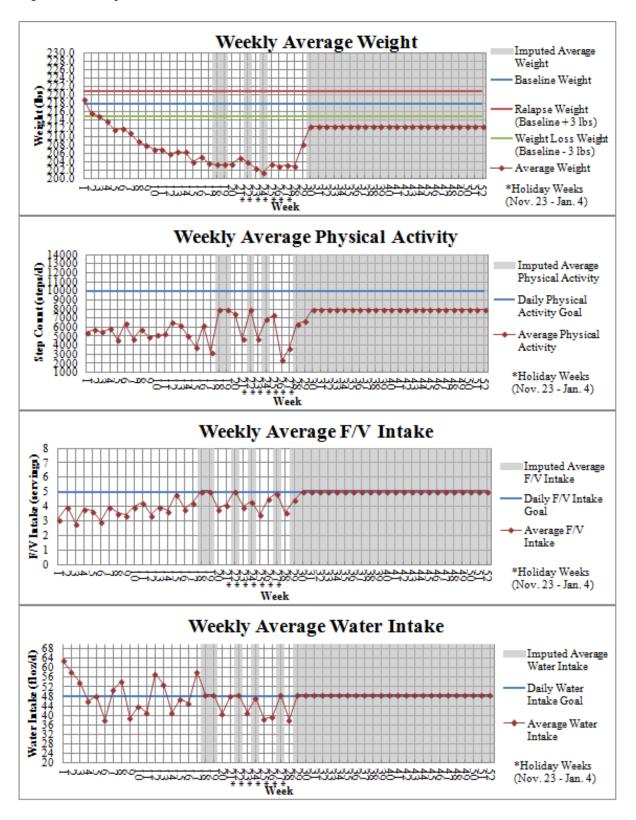


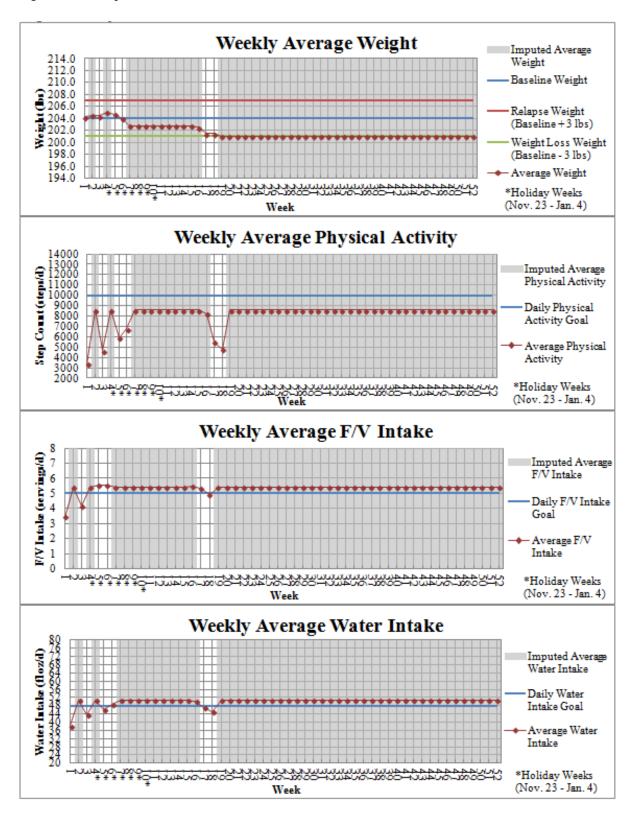




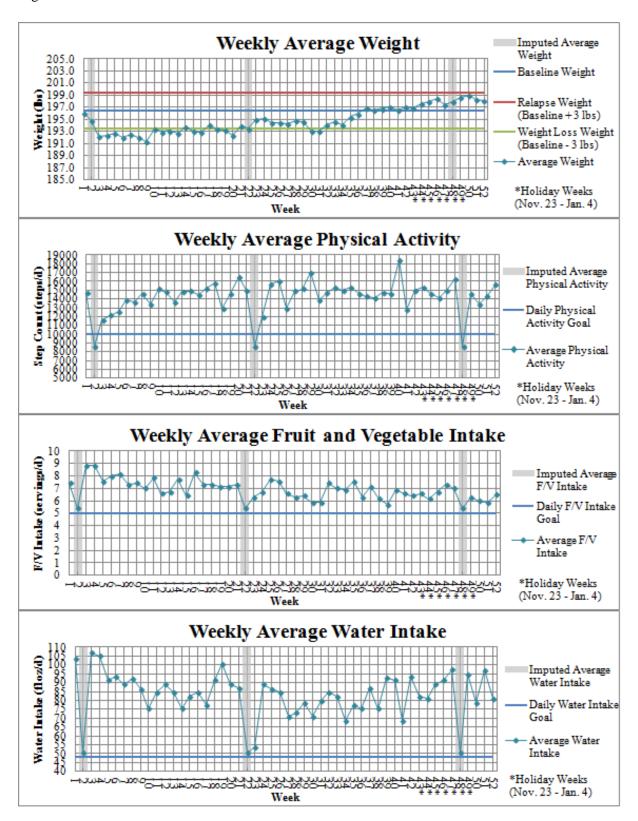


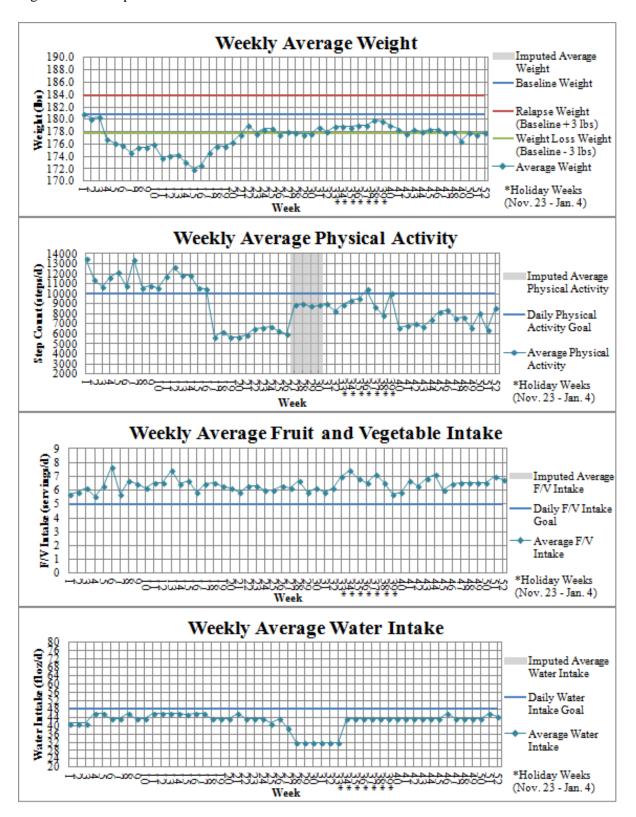


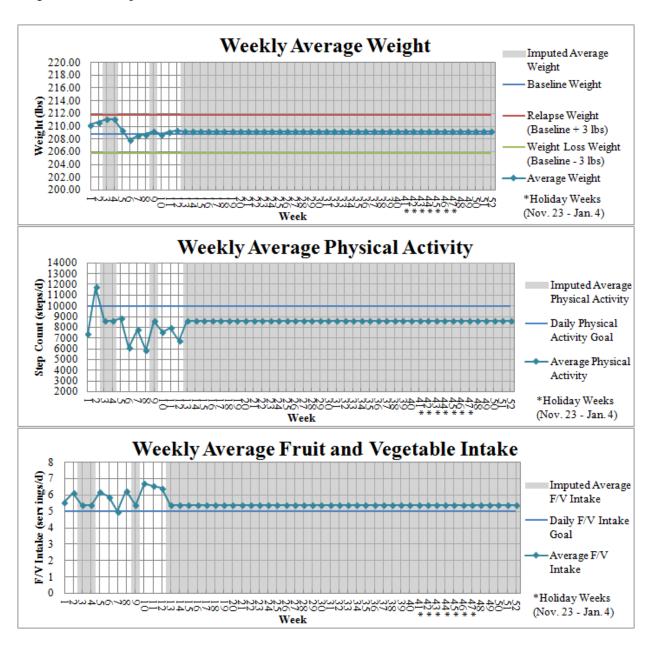


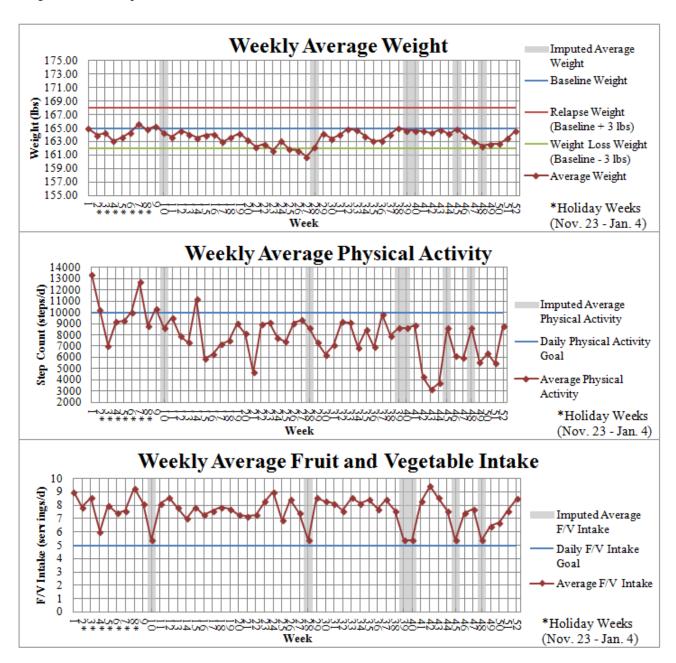


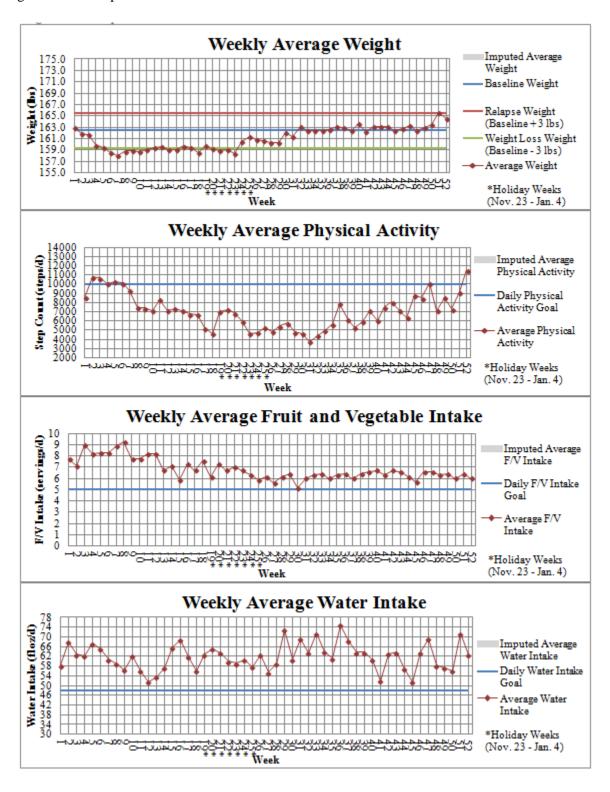
Weight Stable Group

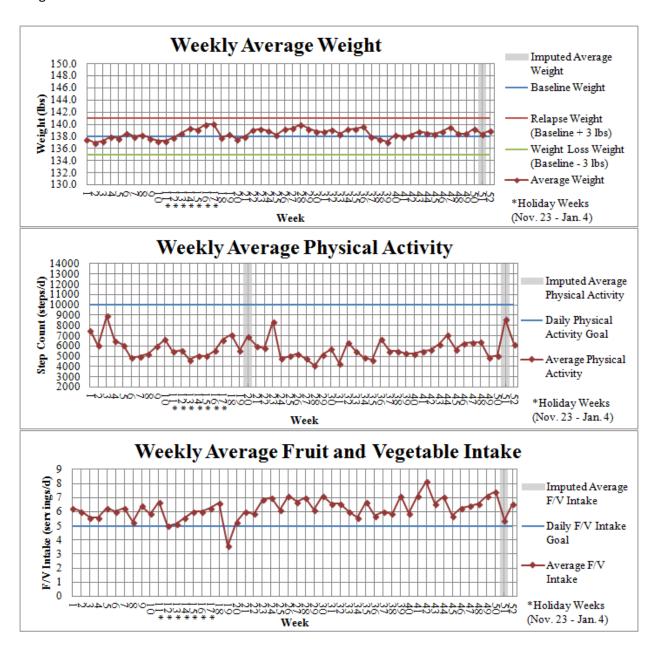


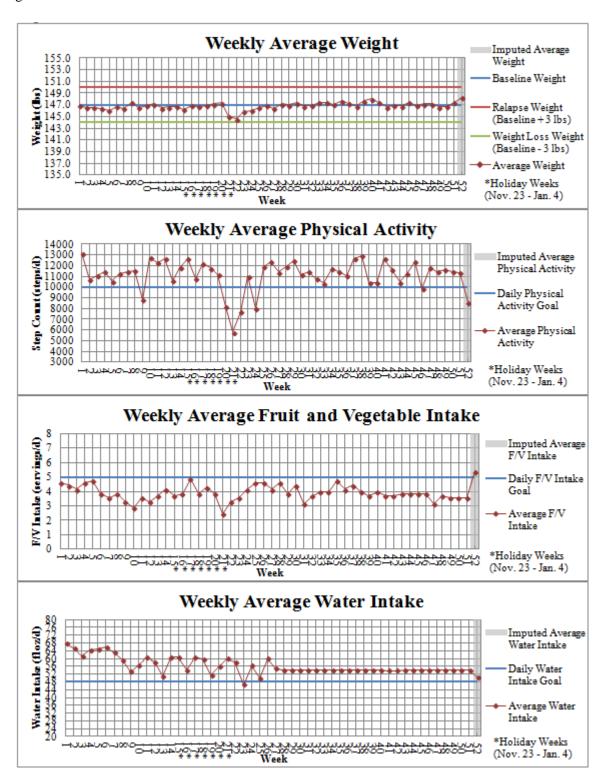


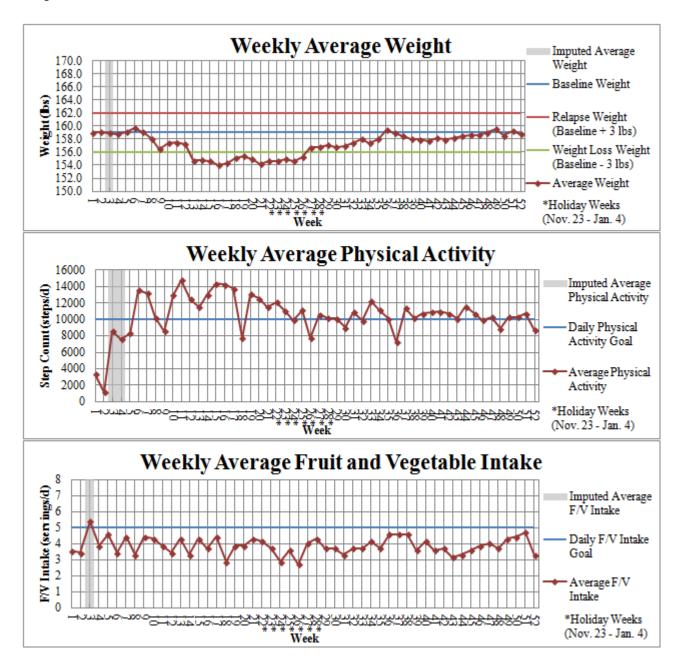




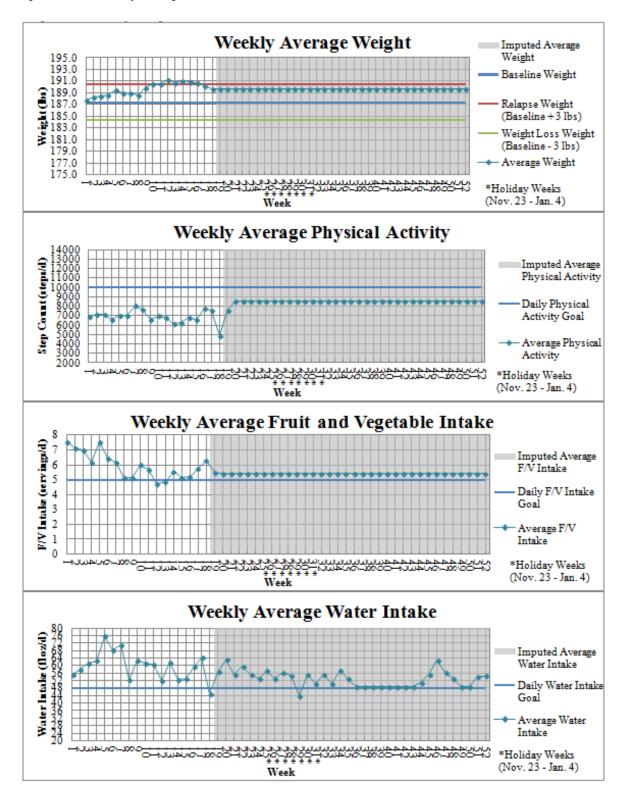


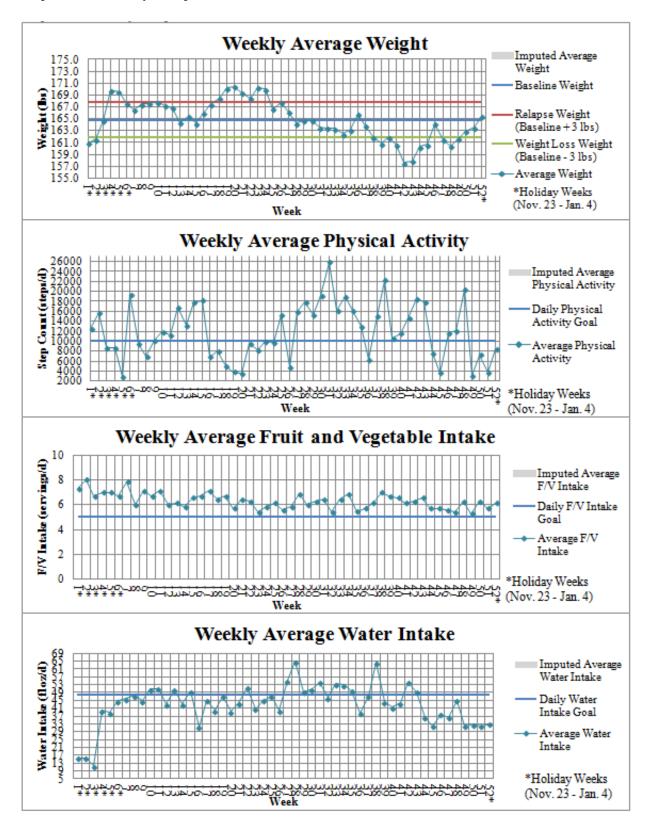


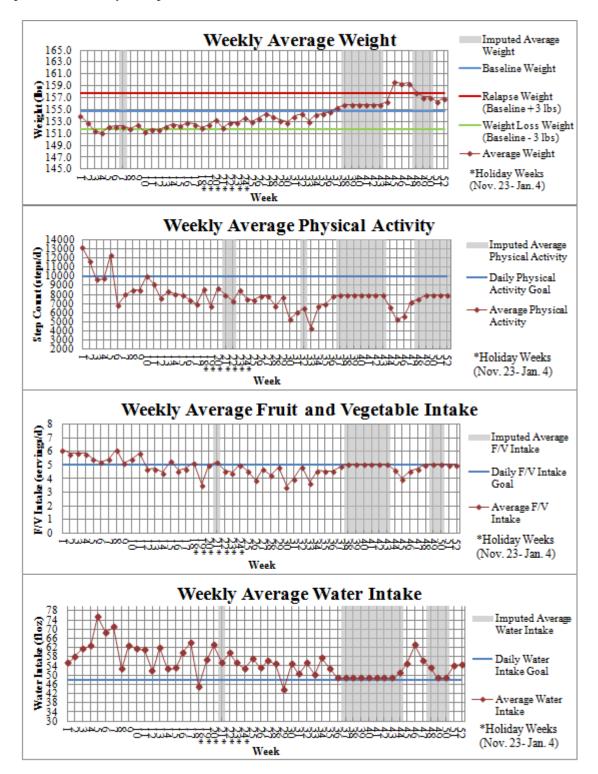


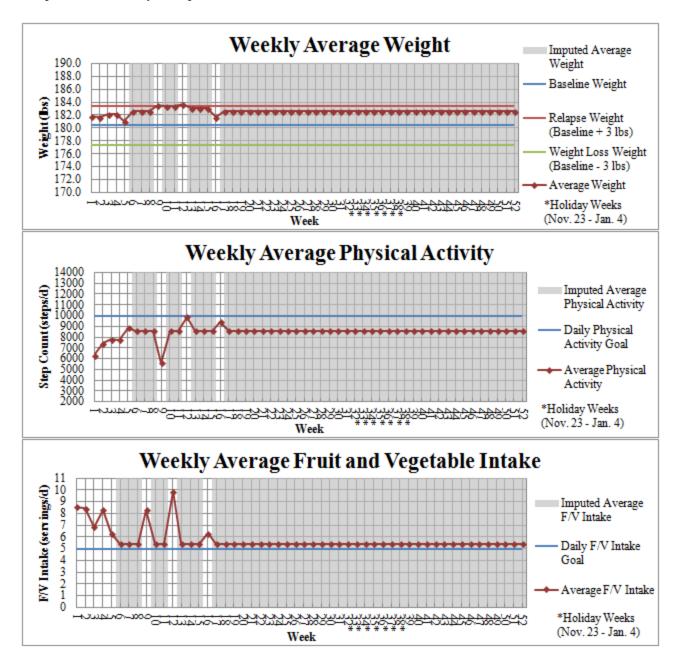


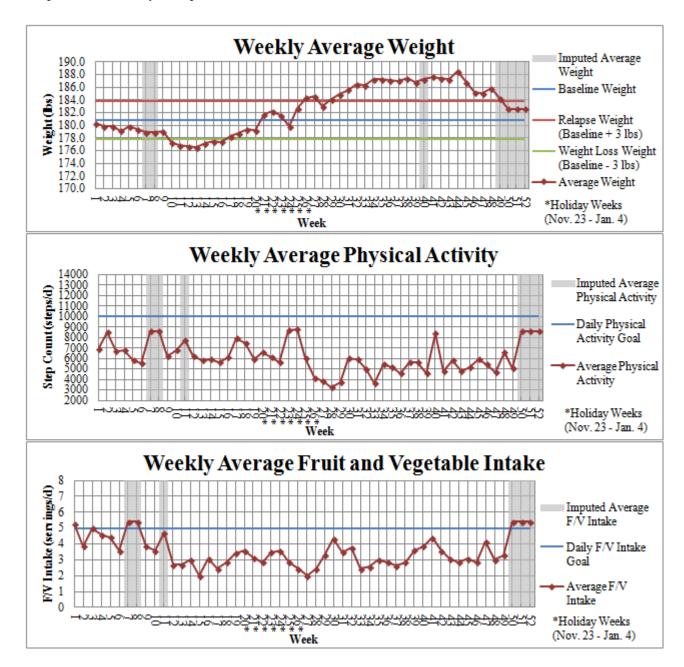
Relapse with Recovery Group

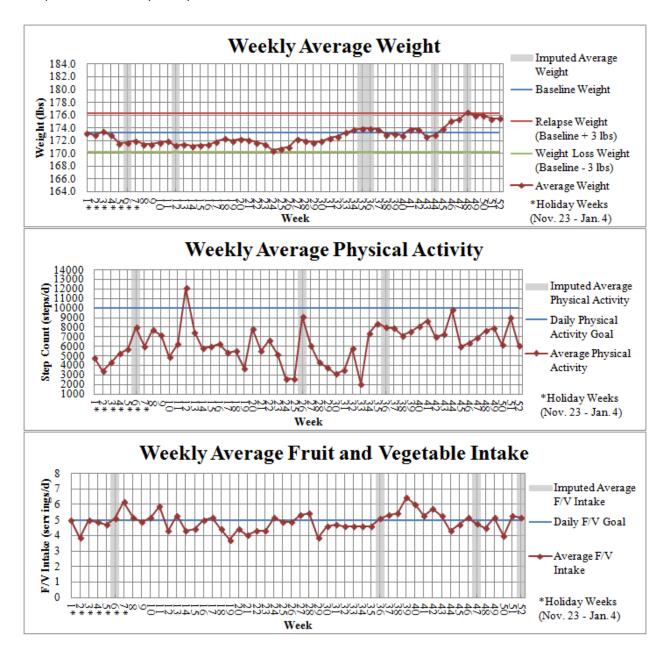


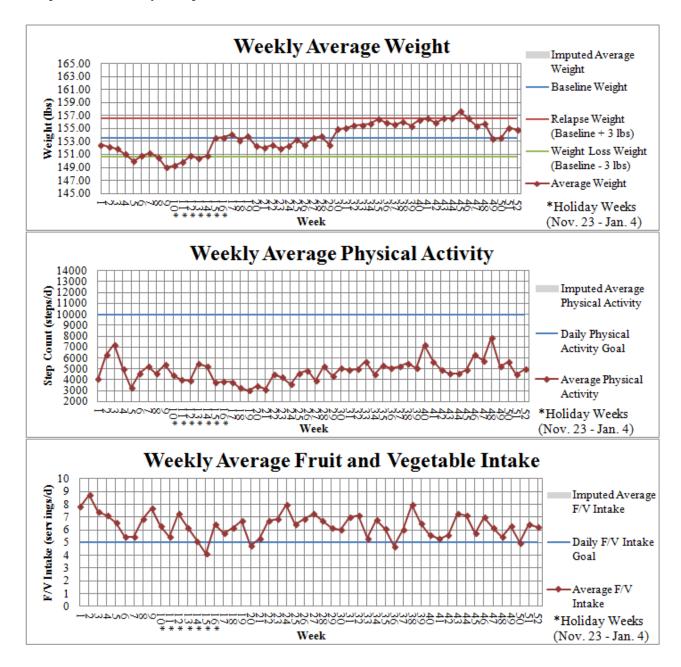


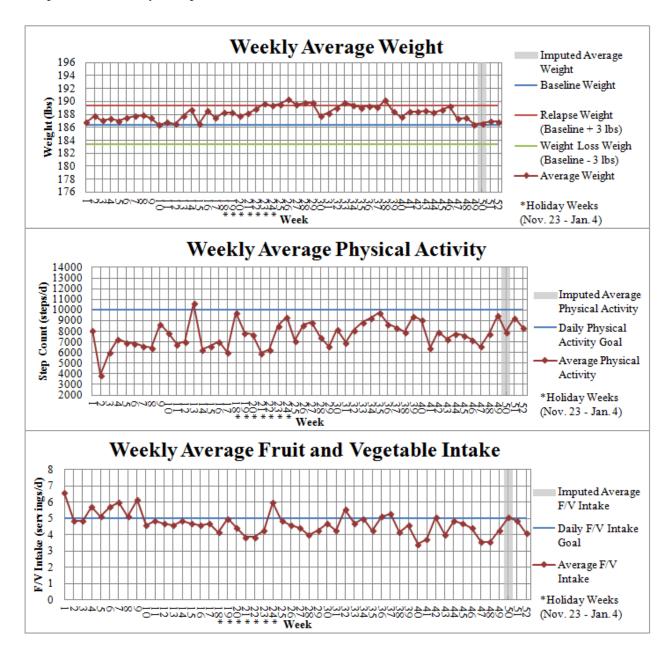












Relapse without Recovery Group

