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Exploring the Role of a Novel Device in Weight Loss Outcomes and Behaviors

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EXPLORING THE ROLE OF A NOVEL DEVICE IN WEIGHT LOSS OUTCOMES AND BEHAVIORS

BY

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ABSTRACT

Obesity is a serious public health problem. There is a need for scalable weight loss interventions that can help people lose weight and decrease their risk of obesity-related chronic disease development. Self-monitoring is a key component of successful weight loss. The Eat Less, Move More (ELMM) device is wrist-worn, and is capable of counting bites by detection of a wrist-roll motion that is specific to eating. The device can also measure seconds between bites, as a proxy to eating rate (ER) measurement, as well as the number of steps taken by the user. The aim of this body of research was to explore the effects of the ELMM device within a weight loss intervention focused on decreasing the size and number of bites, reducing ER, and increasing physical activity, as well as increasing awareness of physiological cues to eating. The first chapter focuses on the examination of the ELMM device-assessed proxy to ER, seconds between bites, with self-reported eating rate (SRER). The average number of seconds between bites as measured by the ELMM device is referred to in this body of work as the bite count interval (BCI). Data from the first three days of participants' use of the ELMM to track bites and BCI were examined, and results showed a significant difference in BCI as measured by the ELMM among SRER categories. These findings suggest that the ELMM is capable of measuring BCI in free-living eating situations, an important first step in establishing the validity of this device in its ability to reflect free-living eating rate. The second chapter explores the effects of a workbook-based weight loss intervention on body weight change (primary outcome), and energy intake (EI), ER, and energy expenditure (secondary

outcomes), with (workbook plus device or WD group) and without (workbook only or WO group) the addition of the self-monitoring ELMM device. There was a strong main effect of time on weight change, but there was no significant difference between groups in body weight change. No significant differences were seen between groups in ER, EI or energy expenditure. At the end of the intervention, participants were dichotomized into a weight loss group (WL) or a weight stable/gainers group (WSG). A strong overall main effect of time, and a significant time by WL/WSG group interaction was seen in scores from the validated weight-related eating questionnaire (WREQ). Post hoc univariate analyses showed a significant effect of time on restraint scores, and a significant time by group interaction on susceptibility to external cues scores. These findings suggest that participants who were most likely to respond to external eating cues, regardless of internal hunger and satiety signals, had more success with this intervention. Chapter three examines changes in resting metabolic rate (RMR) as measured by indirect calorimetry within the weight loss intervention. Secondary outcomes observed changes in substrate oxidation as measured by respiratory exchange ratio (RER), body fat percent, and energy expenditure as estimated by the 7-day Physical Activity Recall (PAR-EE). Exploratory outcomes included the investigation of eating behaviors as measured by the validated Intuitive Eating Scale-2 (IES-2) as they relate to weight loss as a result of the intervention. Pre-post changes in RMR, RER, body fat percent and PAR-EE were not statistically significant. A significant, moderate negative correlation was found between week 8 PAR-EE and week 8 RER. A significant, moderate negative association was also found between week 8 in body fat percent change and RER change. Exploratory outcome results showed a significant time by WL vs. WSG group effect of IES-2 subscale scores, and follow-up univariate analyses showed a significant time by WL vs. WSG effect of the Eating for Physical Reasons rather than Emotional Reasons (EPR) subscale. These results demonstrate that even small changes in body fat percent and energy expenditure from physical activity were associated with beneficial effects on resting fat oxidation. In summary, results from this body of work provide an important first step in examining the validity of the ELMM device in assessing a proxy to free-living eating rate. Moreover, these findings show that an intervention focused on decreasing bites, reducing eating rate, and increasing physical activity is effective for weight loss, and that participants who are more susceptible to external eating cues may be more responsive to this type of intervention. Additionally, participants with increased physical activity after an 8-week weight loss intervention tended to have higher fasting fat oxidation, suggesting that even with minor changes, increased energy expended in physical activity may be associated with greater fat oxidation, which may favor weight loss maintenance. Finally, participants who improved in eating behavior related to the IES-2 Eating for Physical Reasons rather than Emotional Reasons (EPR) subscale, were more successful in weight loss within this type of intervention. This work provides fresh insight into the existing eating rate research, and adds new information to the behavioral weight loss intervention and eating behaviors literature.

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DEDICATION

I dedicate this dissertation to my family.

To my husband Michael, who encouraged me every step of the way and made this journey possible. I love you and am so grateful that you are my partner in this life we have built together. Thank you for believing in me.

To my parents Jane and John, thank you for your unending support. You have shown me what true resilience is.

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PREFACE

This dissertation is presented in Manuscript Format. These projects are part of an ongoing body of research headed by Dr. Kathleen Melanson in the Energy Balance Laboratory at the University of Rhode Island, in the pursuit of finding new ways to help prevent and treat obesity. Each of the three manuscripts presented will be submitted for publication to the specified journals highlighted on each manuscript title page, upon completion of the final dissertation submission. It is an honor to provide even a small contribution to this important research area. It is my hope that with continued ongoing explorations of these topics, important new discoveries might be made into ways that individuals can achieve and maintain healthy body weight, and reduce their risk of chronic disease development.

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CHAPTER ONE

"Examination of an alternate measurement of free-living eating rate with a wearable device"

by

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will be submitted to *Appetite*

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Examination of an alternate measurement of free-living eating rate with a wearable device

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Eating rate, previously defined as consumption of food per unit of time, has been associated with energy intake and obesity. However, eating rate is difficult to measure, necessitating most studies to rely on self-reported eating rate (SRER). The wrist-worn Eat Less Move More (ELMM) device measures seconds between bites, or the average bite count interval (BCI) as a close proxy to eating rate, by detection of a wrist-roll motion specific to eating. The ELMM has not been used to measure BCI in free-living settings. We aimed to examine ELMM-assessed eating rate in free-living settings against SRER. This was a secondary analysis from baseline data of an 8-week weight loss intervention. Participants (n=37; 62.2% female; age 36.5±16.1 years; BMI 31.2±3.5 kg/m^2) ranked their SRER on a 5-point scale. Participants tracked their eating in free-living settings by turning the ELMM on and off at the start and end of meals. The initial three days of BCI data were examined. The five SRER categories were collapsed into three groups: very slow/slow (n=5), medium (n=12), and fast/very fast (n=16). One-way ANOVA examined SRER group differences in BCI, which was found to align with the SRER groups (BCI, M±SD: slow=25.5±4.3, medium=21.0±3.4, and fast=20.8±3.0), and there was a significant difference among SRER groups ($F_{2,20}$=4.1, p=0.03). Tukey tests showed lower BCI, indicating faster eating, in the faster SRER group when compared to those in the slow SRER group (*p*=0.03). A lower BCI, demonstrating faster eating, was also seen in the medium SRER group when compared to the slow SRER group (*p*=0.04), but there was no difference between medium and fast SRER groups (*p*=0.98). No significant relationship was seen between ELMM-measured eating rate and UEM-measured eating rate, or between SRER and in-lab measured eating rate. Future work should consider measuring eating rate with the ELMM device in other populations.

Keywords: Eating rate, wearable device, bite count interval, validation

1. Introduction

Obesity remains highly prevalent in the United States, with approximately 67% of adults classified as overweight, and 35% as obese (1, 2). One behavior that has been associated with obesity is eating rate, or the amount of food consumed per unit of time (3-6). Longitudinal studies have demonstrated a relationship between eating rate and obesity; in a study exploring predictors of weight gain in a sample 438 fire service workers, those who reported a habitual faster eating rate at baseline experienced a significantly increased weight after seven years (5). A systematic review and meta-analysis of 23 studies, mostly cross-sectional, revealed a positive association between eating rate and obesity (3). Population studies have demonstrated a positive association between eating rate and weight gain over time. In a sample of 529 male Japanese workers, those who self-reported as fast eaters had significantly higher weight and BMI at two different time points 8 years apart; furthermore, when compared to slow eaters, the fast eaters gained significantly more weight between the two time points (6). In addition to its establishment as a potential underlying contributor of obesity (3, 7), rapid eating rates have also been positively associated with excess body fat and central fat distribution (8, 9), as well as insulin resistance (10).

Faster eating rates have also been shown to be positively associated with energy intake in experimental studies. In a randomized crossover design examining eating rate and energy intake in both normal weight and obese participants, those in a fast eating condition had a higher energy intake compared to those in a slow eating condition (11). Moreover, decreasing eating rate has been associated with reductions in energy intake in 30 healthy young women (12). A systematic review and meta-analysis demonstrated that slower eating rates led to significantly reduced food intake, and that the measure for eating rate reduction did not matter, as all led to reduced intake (13). Results from that meta-analysis also showed that greater reductions in eating rate were associated with greater reductions in energy intake. This information provides a solid foundation for further consideration of eating rate as a potential key behavior in obesity management.

The use of self-reported eating rate (SRER) can be considered a limitation of most research studies in this area. Given the significance of the relationship between eating rate and obesity and energy intake, new ways to measure eating rate should be explored. However, eating rate is difficult to measure. Only two studies to date have validated SRER against laboratory-measured eating rate (14, 15). One study compared SRER to laboratory measured eating rate in 60 healthy male and female college students (15). That study examined one in-lab meal and three free-living meals. The in-laboratory meal was measured on a universal eating monitor (UEM); food disappearance from the plate in grams and kcalories were divided per minute to measure eating rate. The other three meals were measured by report of meal consumption start and stop times. Participants who self-reported faster eating rate ate significantly faster in the laboratory than those who self-reported slow eating rates. Additionally, in the laboratory, self-reported faster eaters ate significantly faster than those who reported medium paced eating, but no differences were seen in free-living eating rates between SRER categories. Another study demonstrated that SRER was positively associated with measured laboratory eating rate when participants consumed three different foods within one eating occasion in the laboratory (14). However, researchers have not been able to validate free-living eating rate against SRER, because there has previously not been a way to collect eating rate data in free living eating situations. If eating rate can be objectively measured, a new method of self-monitoring for research and weight reduction could be identified.

The ability to self-monitor eating rate quantitatively may be beneficial to those attempting weight reduction. Self-monitoring has been defined as recording dietary intake and physical activity in an effort to increase awareness of current behaviors (16). Self-monitoring is a key component of successful weight loss, and the significance of self-monitoring behaviors in weight loss has been established (17-19). A retrospective analysis found that tracking and recording dietary intake at least three days per week was one of the self-monitoring behaviors that was significantly related to weight loss at 6 months (20). A recent secondary data analysis explored relationships between the frequency of self-monitoring dietary intake with a smartphone application and weight loss, and found that participants in the highest frequency of use group reduced weight significantly more than those with lower use frequency (21). These findings suggest that self-monitoring is associated with weight loss, and increased frequency of this behavior leads to more successful weight reduction outcomes. However, self-monitoring frequency, even with increased ease of use such as with smartphone applications, declines over time (22). The need exists to identify new, easy, intuitive, low effort ways to self-monitor intake, and a device that can measure free-living eating rate may be useful in helping individuals self-monitor this eating behavior.

The Eat Less, Move More (ELMM) device is a tool that counts bites and number of steps taken to track energy intake and expenditure (23). The ELMM is easy to use, can be worn like a watch, and is unique in that it is the only wearable device that can measure bite and step count without record keeping or calorie counting. The device is able to detect bites that occur with a minimum of six seconds between bites (24). It has been validated in both the controlled laboratory setting and in free-living conditions to have a high sensitivity in detecting number of bites taken and a positive, moderate correlation between bites and kilocalories consumed (23, 25). A newer feature of the device is its ability to display the average number of seconds between bites after each eating occasion (24), as a alternative form of eating rate measurement. While this number is not displayed throughout the meal, the user, upon ending the meal, can press a button on the device to see the average number of seconds between bites of that meal. Previously no technology has been available that can assess any measure of eating rate outside of the laboratory, and the application of this device-assessed form of evaluating eating rate in free-living settings has not been previously tested. Therefore this technology needs to be examined in its ability to assess free-living eating rate.

No research to date has explored the validation of a wearable device that can monitor eating rate. Previous research has validated SRER against laboratory-measured eating rate (14, 15), but no research has examined eating rate as assessed by the ELMM device against SRER or laboratory-measured eating rate. Additionally, research has demonstrated that SRER is positively associated with BMI, and that individuals with obesity have been shown to have faster eating rates than those with a healthy BMI (7, 14), yet no study has examined free-living eating rate measurement in individuals with obesity. Therefore the primary aim of this study was to examine free-living eating rate as assessed by the ELMM against SRER in a sample of individuals with overweight or obesity. In the current study, the device tracked number of bites taken and the length of the meal duration of participants. Eating rate as assessed by the ELMM is measured in units of seconds between bites. The average number of seconds between bites per meal is referred to in this paper as the bite count interval (BCI). A lower BCI number indicates a faster eating rate, as there are on average fewer seconds, or less time, between bites throughout the meal. For the purpose of this study, the first three days of recorded eating occasions were examined to measure BCI in free-living settings. The secondary aim of this study was to validate free-living eating rate as assessed by the ELMM against laboratory-measured eating rate. A tertiary objective was to compare laboratory-measured eating rate against SRER in adults with overweight and obesity, which has not yet been previously explored.

2. Methods and Materials

2.1. Study Design and Participants

This was a secondary analysis examining data from the first three days of free-living use of the ELMM device in 37 participants who were recruited and randomized into the experimental group of an eight-week weight loss intervention. Non-smoking, overweight or obese (body mass index [BMI] = 25.0 – 40.0 kg/m^2) participants between the ages of 18 and 60 years who were interested in losing weight were recruited from July 2016 – June 2017 from the University of Rhode Island campus in

Kingston, RI and its surrounding areas. In order to participate in the study, participants had to be free from metabolic disease or conditions that may impact their appetite, including cancer, diabetes, adrenal disease, unmanaged thyroid disease, or eating disorders. Participants were not pregnant or lactating and were not taking any medications that may affect appetite. Participants provided informed written consent to participate in the study, which was approved by the University of Rhode Island's Institutional Review Board.

2.2. Procedures

Participants came into the lab for a total of three individual visits. For the purpose of this validation study, the first two visits are relevant. During the first visit, participants signed an informed consent and anthropometrics were taken to assure eligibility to take part in the study. Participants were given instruction to return to the lab one week later after a 10 hour fast before the scheduled visit. Upon return to the lab for the second visit, and again for the post-intervention visit after 8 weeks, anthropometrics and body composition were measured for descriptive purposes: each participant's height was measured in duplicate using a digital wall-mounted stadiometer (SECA 240, Hamburg, Germany), rounding to 0.1 cm, and the average height of the two measurements was recorded. Weight was measured in duplicate using a digital scale (SECA 700, Hamburg, Germany), rounding to 0.1 kg, and the average of the two measurements was recorded. Waist circumference was measured at the umbilicus in duplicate to 0.1 cm using a Gulick tape (North Coast Medical, Bolingbrook, IL), and the average of the two measurements was recorded. Body composition was measured by air displacement plethysmography (BodPod, Life Measurement Instruments, Concord, CA) following standardized procedures (26, 27).

Once these measures were complete, an ad libitum standardized test meal was served in a separate area of the lab. Participants were offered a choice of oatmeal flavors: maple brown sugar (491.08 grams, 819.6 kcalories, = 1.67 kcalories per gram) or cinnamon spice flavor (=497.1 grams, 845.6 kcalories, 1.70 kcalories per gram). The mixed macronutrient standardized test breakfast consisted of oatmeal enriched with protein powder and mixed with milk and butter to provide 53% carbohydrate, 15% protein and 32% fat as analyzed by the Food Processor SQL (ESHA Research, Salem, OR). Participants were also offered a choice of spring water, hot decaffeinated coffee or hot decaffeinated tea with no additives, and were told to eat as they normally would, until comfortably full. Laboratory breakfast conditions were standardized, as all participants fasted for 10 hours before the meal and were advised to abstain from caffeine as part of the fasting, and to avoid exercise the morning of the laboratory visit. The exact time of start and stop of the test meal were covertly recorded, and the UEM recorded pre- and post-weight of the meal in grams. The beginning and end weights of the meal were also taken using a kitchen digital scale and recorded, and the amounts of oatmeal and water or hot beverage consumed were recorded using weighted differences. Eating rate of the test meal was calculated using both grams and kcalories consumed, divided by the number of minutes of meal duration. After the test meal, participants were educated on how to use the ELMM device outside of the lab, and were instructed to turn it on at the start of each meal and off at the end of each meal.

For the purpose of this study, data from the first three days of recorded eating occasions were examined to measure BCI. This is because no change in bites or eating rate was to take place for that baseline period; any data from a subsequent day may not be an accurate representation of SRER, as participants may have started the eating rate reduction aspect of the intervention. Consequently, the first three days provided the best opportunity to get the most accurate representation of true, pre-intervention, free-living eating rate measurement. If participants did not use the device for a day during the first three days, that day was coded as missing. To assess lab-measured eating rate for the secondary outcome, UEM-measured test meal data from the second laboratory visit were used, as these data were also collected pre-intervention.

2.3. Eat Less, Move More (ELMM) Device

The wrist-worn ELMM device was provided to all participants. This device measures the number of bites taken by the user when the user presses a button to turn the device into bite count mode, and stops counting bites when the user presses the same button to turn off the bite count mode. The device also displays the number of seconds between bites after each eating occasion, as a proxy of eating rate.

2.4. Statistical Analysis

All statistical analyses were performed with SPSS version 24 (Statistical Package for Social Sciences, IBM-SPSS Inc., Armonk, New York). Descriptive statistics were used to summarize demographics using means, standard deviations, frequencies and percentages, and skewness and kurtosis of all variables was examined.

The primary outcome of this study, BCI as measured by the ELMM device, was examined using one-way analysis of variance (ANOVA) to determine group differences among SRER categories. The five eating rate categories were collapsed into three categories due to the low number of participants who self-reported their eating in the extreme categories ("very slow", n = 1, and "very fast", n = 6). Therefore the "very slow" and "slow" categories were combined into one "slow" category, and the "fast" and "very fast" categories were combined into one "fast" category. Box plots and stem-and-leaf diagrams were used to identify potential outliers; one high influential outlier was identified in the 3-day average BCI analysis. However, this outlier was kept for all analyses, because eating rate measurement is a novel practice, and no justification could be made to remove the participant from the analyses. The average BCI for this participant was 32.0, which is within the parameters established by our research team as an acceptable measurement after working with data collection and BCI data analysis for 17 months. Common BCI ranges included measurements between 13-43, with some more extreme values falling as fast as 10 and as slow as 52 average seconds between bites. Pearson's correlations explored secondary outcome associations between ELMM-measured eating rate and UEM-measured eating rate. One-way ANOVA and Spearman's correlations examined tertiary outcome SRER group differences and associations among UEM-measured eating rate and SRER categories. All statistical tests were two-tailed, and considered significant with p values of < 0.05.

3. Results

Participant characteristics are presented in Table 1. Participants (n=37) were primarily women (62.2%), Caucasian (69%), had a mean age of 37.7 ± 15.3 years, and a mean BMI of 31.3 ± 3.2 kg/m^2. There were no statistically significant differences among SRER groups in age, BMI, anthropometrics, race or ethnicity.

Results for the primary outcome of ELMM-measured eating rate, as measured by BCI, are presented in Figure 1. ELMM-measured eating rate, in average BCI (mean ± SD) according to the three SRER groups, were: slow=25.5±4.3, medium=21.0±3.4, and fast=20.8±3.0 seconds between bites. There was a significant difference among SRER groups ($F_{2,20}$=4.1, *p*=0.03, partial η^2 = 0.22). Post-hoc Tukey tests showed that participants in the fast SRER group had a significantly lower BCI (indicating fewer average seconds between bites) than those in the slow SRER group (*p*=0.03). Participants in the medium SRER group had a significantly lower BCI (indicating fewer average seconds between bites) than those in the slow SRER group (*p*=0.04), but there was no significant difference in BCI between medium and fast SRER groups (*p*=0.98). Spearman's correlations showed no significant association between ELMM-measured eating rate and SRER (*r*=-0.28, *p*=0.12).

For analyses of in-laboratory eating rate as measured by the UEM, the calculation of eating rate was performed using both grams of food consumed per minute, as well as kcalories consumed per minute. Higher numbers indicate faster eating rates, as there are more grams or kcalories being consumed per minute throughout the meal. (This is the opposite of BCI measurement in ELMM-measured eating rate.) There were no significant associations between free-living eating rate, as measured by the ELMM, and laboratory measured eating rate, as measured by the UEM, in grams per minute (r = -0.30, p = 0.09) or in kcalories per minute (r = -0.28, p = 0.12). Table 2 shows tertiary outcome results for UEM-measured eating rate in grams per minute and kcalories per minute by SRER category. There were no significant differences in laboratory-measured eating rate among SRER categories as measured by the UEM in grams per minute ($F_{2,34}$=1.35, p=0.27), or in kcalories per minute ($F_{2,33}$=1.05, p=0.36); however, a medium effect size was seen in both (partial η^2 = 0.07 and 0.06 for grams/minute and kcalories/minute, respectively). No significant associations were found between UEM-measured eating rate in grams/minute and SRER (r = 0.26, p = 0.12).

4. Discussion

Findings from this study demonstrate that in 37 participants with overweight and obesity who used the device, the ELMM was able to provide BCI information as a proxy to eating rate measurement over three days of free-living eating occasions. Until now, there has been no way to assess eating rate in free-living settings. In this study, free-living eating rate assessed as BCI by the ELMM corresponded with the three SRER categories of participants in our study, and there was a significant difference in BCI among eating rate categories. To our knowledge, this study is the first to investigate the relationship between eating rate as assessed by the ELMM device and SRER. The ELMM device assesses eating rate by recording number of seconds between bites; the larger the number, the slower the rate of eating, which is reflective of longer pauses between bites, a behavior that is advocated for slower eating.

A previous version of the ELMM device, the Bite Counter, was used in a laboratory study in which participants consumed three meals under three conditions: a meal with no feedback, a meal in which participants received bite-rate feedback, and a meal in which participants were given a 50% bite-rate reduction goal (28). The study found that participants ate 70 fewer kcalories in the slow bite-rate meal when compared to the meal in which they received bite-rate feedback (28). However, although participants wore the device during all three meals, the device did not actually measure bite rate; instead, the researcher covertly observed the participants, and hit a computer key with each bite taken, which was displayed on a computer screen for the patrticipants. Therefore, the present study is the first to apply the eating rate function of the ELMM device, because this aspect of the device has not been previously tested within the laboratory setting or in free-living settings.

To our knowledge, the only study prior to the current one to validate free-living eating rate against SRER was by Petty and colleagues, who found no differences among SRER categories in three free-living meals (15). In that study, information was collected about three free-living meals, in an effort to validate free-living eating rate as reported by participants against SRER on a baseline questionnaire. This measure of free-living eating rate, however, was by self-report of start and stop times of each meal from a one-day food record, because at that time there was no objective way to measure free-living eating rate. Accurate food record keeping and dietary recall assumes knowledge on the part of the participant about food, portion sizes, and relies heavily on memory. Dietary recall has historically been regarded as a suboptimal means of obtaining information about consumption due to inaccuracy (29-31). There is also lack of accuracy in reporting meal duration, and the additional estimation of kcalories per minute of meal duration may further compound this inaccuracy. For these reasons, differences between fast and slow eaters in reported eating rate from free-living meals may go undetected. Given the difficulty and inaccuracy of self-report, the need has existed for an objective measure of free-living eating rate, and this need was highlighted by the findings on self-reported eating rate of individual meals from that study (15). Therefore, the ability the ELMM to tangibly reflect free-living eating rate is an important first step toward more a more objective measure of free-living eating rate.

In the current study, a significant difference was found in ELMM-measured free-living eating rate between slow and medium eaters, and between slow and fast eaters, but there was no significant difference between medium and fast eaters. This may be because we recruited participants with a BMI of 27-40 kg/m^2, most of whom self-reported as medium or fast eaters, which is consistent with the literature demonstrating the positive association between faster eating rates and BMI (7, 14). This may also be due to a limitation of the device, in that the minimum time detected between bites by the ELMM is six seconds (24); therefore, if participants were eating faster than this, it is possible that bites may have gone undetected. Therefore, this limitation requires a cautious interpretation of the lack of a significant difference between medium and fast self-reported eating categories.

The present study did not find significant associations between free-living eating rate as measured by the ELMM and laboratory-measured eating rate as measured by the UEM. While the UEM is considered to be a valid tool to measure in-laboratory eating rate due to good test-retest reliability (32), it is important to note that we compared in-laboratory eating rate with free-living eating rate as measured by the ELMM device. These two types of eating occasions differ. The UEM-measured eating rate was done under standardized laboratory conditions, which is not representative of real-world eating conditions. Moreover, the UEM measures food disappearance in grams or kcalories, but the ELMM does not because it is not able to detect bite size. Additionally, the UEM-measured eating rate was based on one meal only, and the meal was pre-selected for the participants. In comparison, the present study assessed ELMM-measured eating rate by using three days of eating occasions from free-living settings, in which participants had the ability to self-select their own foods, and it has been established in the laboratory setting that different foods are consumed at different eating rates (33-35). These differences may account for why we found no significant correlations between the two different types of measures.

The present study did not find significant differences between the UEM-measured laboratory eating rate of participants with overweight and obesity, and SRER categories. There may be a few different reasons for this. Petty and colleagues demonstrated that eating rate as measured in the laboratory, using the UEM, aligned with SRER in a study with 60 healthy weight participants, who were selected by study design to measure eating rate across eating rate category groups (15). To this end, the research group selected approximately 20 participants per group from an online survey that was part of a larger study. This group found significant differences in UEM-measured eating rate among SRER categories. Our study did not show these differences, but we did see a medium effect size as demonstrated by a univariate eta squared value of 0.07, which suggests that with additional participants we may have seen statistical significance. Additionally, we had an uneven group distribution, as this was a secondary data analysis and the primary outcomes for the study were centered around weight loss, not eating rate validation. Future studies may consider recruiting a larger number of participants and stratifying them according to eating rate category, in an effort to establish an even distribution among eating rate categories. Additionally, the meal offered in the present study was a breakfast meal after a 10-hour fast, and the meal offered in the Petty and colleagues study was a pasta-based lunch after a 4-hour fast following a standardized breakfast at home (15). Therefore, lack of an adequate number of participants in each group and differences in meal type, timing and conditions under which participants consumed the meal may have contributed to differences in results.

There may be differences between the eating rates as well as SRER perceptions of healthy weight individuals when compared to those with obesity. One of the first studies to identify a significant positive association between eating rate and BMI was identified in a sample of 1,695 18-year old healthy BMI Japanese dietetic students (7). In that study, results demonstrated that there was a significant increase in BMI with each increase in SRER category, even within the healthy weight range of BMI (7). Van den Boer and colleagues also found that self-reported fast eaters were at a higher risk for being overweight compared to self-reported average plus slow-speed eaters, with an adjusted odds ratio of 1.73 (95% CI: 1.38, 2.17) in a Dutch population study (14). The study by Petty and colleagues also had a sample of college-aged participants with a BMI range of ~ 20 – 29 kg/m^2, whereas our study enrolled a wider age range of only overweight and obese participants.

Within that publication, van den Boer and colleagues also compared SRER and laboratory-measured eating rate in 57 adults (14). In that study, a self-administered questionnaire, which included a question on eating rate ("How would you describe your eating rate compared with others?" Categories were very slow, slow, average, fast, or very fast) on eating behavior, was given to participants. Actual eating rate was measured for three food products (soft bun with cheese, apple, and vanilla custard), and satiety VAS scales were completed before and after the consumption of each food. That study found that laboratory measured eating rate increased proportionately and significantly (all p<0.01) with SRER for all three food products measured. Post hoc analyses were conducted and these demonstrated that self-reported fast eaters had a significantly higher eating rate when compared to self-reported slow and average speed eaters, but no significant differences were found in eating rate between slow and average speed eaters. Therefore, the results demonstrated that SRER was positively associated with measured laboratory eating rate. However, this population differed from that in the present study because those participants were younger on average (mean age, 22.6 ± 2.8 years) and were healthy weight participants (mean BMI, 22.1 ± 2.8 kg/m^2) whereas the participants from the present study were older on average (mean age, 36.5±16.1 years), and overweight or obese (mean BMI, 31.2±3.5 kg/m^2). Thus, this study was the first to attempt comparisons of SRER in participants with overweight and obesity, and we saw a medium effect size in our analyses. A larger sample might be beneficial to support the findings for this outcome in the future.

While both of these studies were able to validate laboratory measured eating rate against SRER, it is important to consider that the laboratory is not a natural setting, and participants may alter their rate of eating as a result of being in an unfamiliar place and feeling like they were being observed. The ELMM device allows for tracking of this metric easily and in a non-obtrusive manner. Therefore the examination of its ability to assess eating rate in real world settings is an important next step in helping researchers gain a better understanding of eating rate in free-living settings.

Our study also used a collapsed SRER scale, due to the low numbers of participants in either of the extreme eating rate categories. This has been done previously in the literature (15, 36). In a study published in 2008 by Maruyama and colleagues in Japan, associations between eating until full and eating quickly with overweight were explored in a sample of 3287 adults (1122 men, 2165 women) from two communities in Japan (36). The instrument used was a validated self-administered brief questionnaire on diet history; asked whether they usually eat until full (yes/no question) and what their usual speed of eating category is out of five categories: very slow, slow, medium, fast, or very fast; due to low number of participants who self-rated in the very fast category, the very fast and fast categories were combined into an eating quickly category. Categories of medium, slow and very slow were also combined to make a slower eating category. Another study used this questionnaire when validating SRER against friend-reported eating rate; results showed good agreement between participant and friend-reported eating rate using this instrument

(7); that study was the closest to a validation study of SRER until Petty and colleagues validated SRER with laboratory measured eating rate (15).

Our study had many strengths, including the ability for the researchers to obtain and review recorded data sheets sent via email from participants who downloaded these data using the software that accompanies the device. We assessed free-living eating rate using the first available wearable device capable of such measurement. Limitations of our study include a mild lack of compliance among some of the participants, as was evidenced by data analysis. For any days in which participants did not use the device during this first three-day period, the data were coded as missing, and the average of the days that were available from these first three days was taken. Another limitation is the widely Caucasian sample, which may make it difficult to generalize to other populations. However, our sample encompassed a wide range of ages from 18 – 60, which makes the findings more generalizable to different adult age groups. Finally, this study recruited participants with overweight and obesity, and further validation of the ELMM device as an appropriate and accurate tool to measure free-living eating rate should be conducted in other populations including those in the healthy BMI range. However, it is within populations with overweight and obesity that eating rate research is most needed.

Eating rate has been shown to affect obesity-related conditions including high body mass index, glucose intolerance, and undesirable adipose distribution (3, 4, 9, 10), as well as energy intake and reduction (11-13). Eating rate as a changeable behavior may inform future programs that address energy intake reduction and weight management strategies. Finding new ways to measure eating rate in free-living settings is an important step in pursuing this avenue of energy intake and weight management, and this study was the first to show that eating rate as assessed by the novel ELMM device aligned with SRER. Future work may consider recruiting participants based on SRER category to further examine assessment of eating rate by the ELMM device.

5. Conclusion

In summary, our results provide the first efforts to examine free-living eating rate as assessed by the ELMM device against SRER. The ELMM device measured seconds between bites, or average BCI, during eating occasions, and BCI measured by this device corresponded to SRER. We did not see the same level of correspondence between ELMM measured eating rate and laboratory measured eating rate, or between laboratory-measured eating rate and SRER, but the medium effect sizes seen in the present study suggest that future research is warranted in this area. Future studies should be designed to recruit larger, equal size samples within each eating rate category for analysis of BCI and its comparison to SRER and laboratory measured eating rate. Future directions should also consider assessing eating rate with the ELMM device in other populations.

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Contributors

K. Melanson, G. Greene and J. Beatty were responsible for design of the experiment. K. Melanson and G. Greene proofread the manuscript and provided valuable feedback. J. Beatty supervised the collection of data, analyzed the data, and wrote the manuscript.

Conflict of interest

There are no conflicts of interest.

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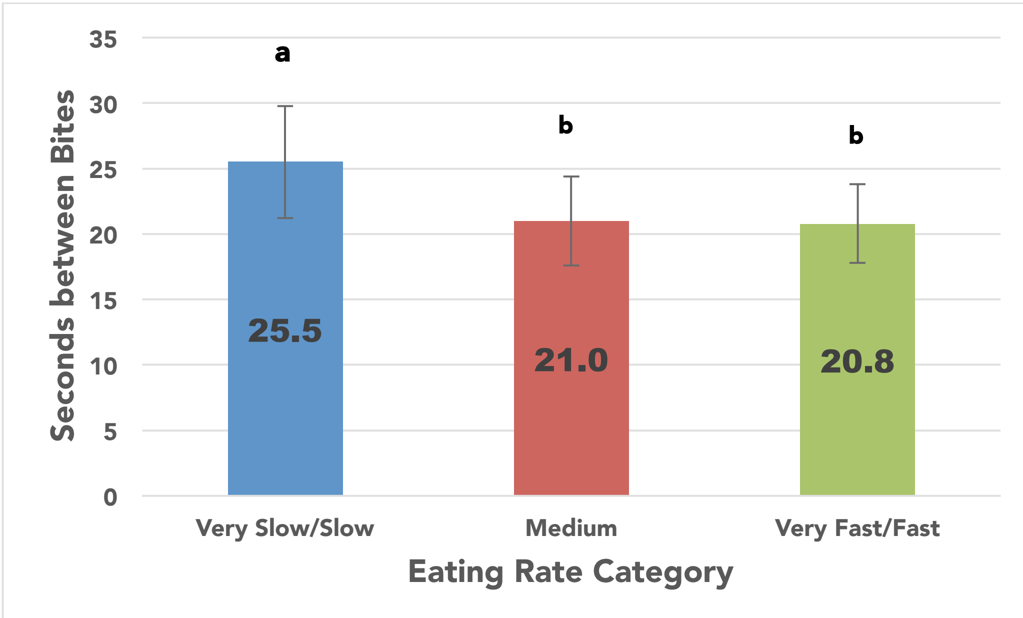
Chapter One Tables and Figures

Table 1. Participant characteristics.

Characteristic	(n=37)
Mean±SD	
Age, years	36.5±16.1
Body mass index (kg/m^2)	31.2±3.5
Body fat (%)	36.8±8.6
Sex, n(%)	
Male	14(37.8)
Female	23(62.2)
Ethnicity, n(%)	
Hispanic or Latino	2(5.4)
Not Hispanic or Latino	29(78.4)
No answer	6(16.2)
Race, n(%)	
American Indian or Alaskan Native	0
Asian	6(16.2)
Black or African American	2(5.4)
Caucasian	26(70.3)
Other	1(2.7)
No answer	2(5.4)

Figure 1. Primary outcome results: Bite count interval (BCI) by self-reported eating rate (SRER) category.



One-way ANOVA examined group differences in free-living eating rate as measured by the Eat Less Move More (ELMM) device. Higher numbers (bite count interval measured in seconds between bites units) denote slower eating rates, while lower numbers show faster eating rates. Post hoc Tukey tests show differences between each SRER category. a = $p<0.05$: Very slow/slow compared to Medium; b = $p<0.05$: Very slow/slow compared to Fast/very fast

Table 2. In-laboratory measured eating rate by SRER category.

SRER Category	N	UEM measured eating rate in grams/minute (Mean ± SD)	*p* value	Eta squared	UEM measured eating rate in kcals/minute (Mean ± SD)	*p* value	Eta squared
Category			0.27	0.07		0.36	0.06
Very slow/slow	5	23.9±13.9			40.0±23.1		
Medium	15	31.6±16.1			53.3±27.0		
Fast/very fast	16	36.8±16.4			59.3±26.3		

One-way ANOVA examined group differences in universal eating monitor (UEM)-measured eating rate between self-reported eating rate (SRER) categories. Higher numbers (kcalories per minute) denote faster eating rates, while lower numbers show represent slower eating rates.

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CHAPTER TWO

"Effects of a novel bites, steps, and eating rate-focused weight loss intervention"

by

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Effects of a novel bites, steps, and eating rate-focused weight loss intervention

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Abstract

Obesity continues to be a serious public health problem. Eating rate (ER), defined as the amount of food consumed per unit of time, has been associated with obesity and energy intake (EI). However, there have been limited interventions focused on reducing ER and bite count, and increasing physical activity. This study aimed to explore effects of a multifaceted 8-week weight loss intervention that focused on weight change (primary outcome), and EI, ER, and energy expenditure (secondary outcomes), with and without a self-monitoring wearable device. Tertiary outcomes included examining the effects of the intervention on eating behaviors as measured by the Weight Related Eating Questionnaire (WREQ), a validated tool assessing eating behaviors on four subscales: routine restraint (RR), compensatory restraint (CR), susceptibility to external cues (SEC) and emotional eating (EmE). Seventy-two adults with overweight or obesity (age, 37.7±15.3 years; BMI, 31.3±3.2 kg/m^2) were randomized into two groups: intervention workbook only (WO), or intervention workbook plus device (WD). Three multiple-pass 24-hour dietary recalls were obtained, both before Week 0 and Week 8. Participants were weighed and measured, consumed a test meal, and completed the WREQ and the 7-day Physical Activity Recall (PAR), all under standardized laboratory conditions at Week 0 and Week 8. Repeated measures ANOVA examined the primary outcome of weight change between groups, and 2X2 repeated measures MANOVA examined secondary outcomes of ER, EI, and energy expenditure. A 2X2 repeated measures MANOVA examined effects of the two time points and two groups on WREQ scores. Correlations were run between WREQ scores and body weight change. There was no significant difference between WO and WD groups in weight change, but there was a strong main effect of time on weight change. No significant differences were seen between groups in ER, EI or energy expenditure, but there was a significant main effect of time. There was also a significant main effect of time on WREQ scores. At week 8, participants were dichotomized into a weight loss group (WL) or a weight stable/gainers group (WSG). A strong overall main effect of time, and a significant time by WL/WSG group interaction was seen in WREQ scores. Post hoc univariate analyses showed a significant effect of time on restraint scores, and a significant time by group interaction on SEC scores. These findings suggest that an intervention focused on reducing eating rate and bite count, and increasing steps, is effective for weight loss. Additionally, participants who are more susceptible to external eating cues may be more responsive to this intervention. Future weight loss studies may consider this type of intervention for participants who are more prone to eating in response to external cues that are independent of internal hunger and satiety indicators.

Keywords: Eating behaviors, external eating, wearable device, questionnaire, weight loss

1. Introduction

Obesity continues to be a serious public health problem. It is currently estimated that 67% of all adults in the United States (US) are overweight, and 35% are obese (1, 2). Achieving a modest weight loss of 5% may reduce many risk factors associated with overweight and obesity (37, 38), but weight loss can be difficult due to the increased accessibility of highly palatable foods that are low in nutrient density and high in energy, which has increased dramatically over the last 30 years (39-41). A prospective study examining relationships between multiple lifestyle factors and long-term weight gain demonstrated that over a 4-year period, participants gained an average of 3.4 pounds, and that this weight gain was positively associated with increased intake of energy dense foods (42). Two primary contributing factors to obesity include excess food consumption (42), and the obesogenic environment that currently exists in developed countries, which is related to excess food consumption (43).

The obesogenic environment has been defined as “the sum of influences that the surroundings, opportunities, or conditions of life have on promoting obesity in individuals or populations” (44). The presence of external food-related cues that promote intake of highly palatable, energy dense foods are abundant in this environment. Moreover, external food-related cues have been shown to cause individuals to override internal signals of satiety and eat if food is readily available in the environment, and the availability of novel foods and food abundance leads to suppression of satiety cues and overeating (39). More energy dense and readily available foods are being produced, and these foods are being marketed more heavily than ever before (45). These factors can make it difficult to regulate EI. Energy balance is defined as an equilibrium between EI and energy expenditure, and because weight gain is the result of more energy being consumed than expended (46), finding ways to promote reduced EI and increased energy expenditure has been the focus of most previous weight loss interventions.

One promising way to help reduce EI is by slowing down eating rate (ER) (12, 13). Defined as the amount of food consumed per unit of time, ER is a behavior that has been associated with obesity (3): faster ERs have been positively associated with higher body mass index (BMI) (3, 14). Faster ERs have also been shown to be positively associated with EI in experimental studies (13). In a randomized crossover design examining ER and EI in both normal weight and obese participants, those in a fast eating condition had a higher EI compared to those in a slow eating condition (11). Moreover, decreasing ER has been associated with reductions in EI in 30 healthy young women (12). A systematic review and meta-analysis demonstrated that greater reductions in ER were associated with greater reductions in EI (13). This information provides a solid foundation for further consideration of ER as a potential key behavior in obesity management.

Small within-laboratory studies conducted in the Energy Balance Lab at the University of Rhode Island have shown that higher ERs are associated with increased EI, and that ER is a behavior that can be changed with education, resulting in a significant decrease in ER (47) and EI (47, 48). In a study examining the effects of one-on-one coaching to reduce ER in the laboratory setting, Matsumuto and colleagues demonstrated that slowing ER led to a significant reduction in EI (48).

Expanding this coaching and education to a small laboratory group setting of overweight young women, the same researchers demonstrated that this education led to reduced ER in a group setting as well (47). Such findings are promising to obesity-related research, because they present a behavior that is changeable and that may potentially affect EI, which is a critically important component of obesity prevention and treatment. However, the techniques found to be successful in teaching individuals to reduce ER in the lab have not been tested in a larger group of individuals in free-living settings, and the relationship between reducing ER and weight loss has not yet been explored. Furthermore, the effects of an intervention focused on reducing EI by decreasing bites and reducing ER, while increasing physical activity, has not been previously tested.

This weight loss intervention largely reflects the self-regulation component of SCT, in that self-monitoring, goal setting and feedback are main features of the intervention. Social Cognitive Theory (SCT) is a behavioral theory developed by Albert Bandura (49). This theory has been extended to include the construct known as reciprocal determinism, which proposes an interaction among personal factors, behavior, and environmental factors, each of which influence and are influenced by each other (49). The personal and environmental factors form the main constructs of the theory and include psychological determinants, environmental determinants, observational learning, and self-regulation (50, 51). The intervention used in this study is founded within self-regulating elements of the SCT. The main aspect of the intervention is a workbook that focuses on three metrics: reducing number and size of bites taken, decreasing rate of eating, and increasing the number of steps taken on a daily basis. The goal of the workbook was to change behaviors related to eating and physical activity, such that a resultant change in body weight and other secondary outcomes would occur. The self-regulation piece of the SCT encompasses self-monitoring, goal setting and feedback as well as self-efficacy, or the belief in one's ability to perform the new behavior (49-52).

The primary purpose of this study, outlined in Figure 1, was to explore the efficacy of an eight-week weight loss intervention focused on a novel combination of reducing bites, reducing ER, and increasing steps as a modality of increasing energy expenditure on body weight change. Moreover, we sought to examine whether the addition of a wearable self-monitoring device, the Eat Less, Move More device (ELMM), would increase weight loss. The ELMM is easy to use, can be worn like a watch, and is unique in that it is the only wearable device that can measure bite step count without record keeping or calorie counting. It has been validated in both the controlled laboratory setting (23) and in free-living conditions (25) to have a high sensitivity in detecting number of bites taken and a positive, moderate correlation between bites and kilocalories consumed. The device is also able to display the average number of seconds between bites after each eating occasion, as a proxy measure of eating rate (24). Due to the ability of the ELMM to provide the ability to self-monitor the specific metrics of the intervention (bites, ER and steps), we hypothesized that participants with the ELMM and the intervention workbook for the present study would lose more weight than the participants who were receiving the intervention workbook alone. Secondary aims of this study were to assess the effects of this novel intervention focused on bites, ER and steps on EI, ER, and energy expenditure as measured by the 7-day physical activity recall (PAR-EE). We hypothesized that participants who lose weight would demonstrate significant reductions in EI and ER, and a significant increase in PAR-EE, as a result of the intervention. Tertiary outcomes included examining the effects of the intervention workbook on eating behaviors as measured by scores of the Weight-Related Eating Questionnaire (WREQ) (53). We hypothesized that those who scored higher in susceptibility to external cues would be the most responsive to the intervention, as measured by weight loss, because much of the intervention encourages individuals to slow eating rate and increase awareness of their internal eating cues and responses. We anticipated less change in restrained and emotional eating scores, as these behaviors were not primary targets of the intervention.

2. Methods

2.1. Study Design and Participants

This was a weight loss intervention in which 77 participants were recruited to participate in an eight-week self-led program focused on reducing bites, reducing ER, and increasing steps. Additionally, half of the participants were randomized to the use of the ELMM to track these metrics. Non-smoking, overweight or obese (body mass index [BMI] = 25.0 – 40.0 kg/m^2) participants between the ages of 18 and 60 years who were interested in losing weight were recruited to participate in the study from July 2016 – June 2017 from the University of Rhode Island campus in Kingston, RI and the surrounding community. Participants had to be free from metabolic disease or conditions that may impact their appetite, including cancer, diabetes, adrenal disease, unmanaged thyroid disease, or eating disorders. Participants were not pregnant or lactating and were not taking any medications that may affect appetite. Participants provided informed written consent to participate in the study, which was approved by the University of Rhode Island's Institutional Review Board.

2.2. Procedures

Participants were screened by phone, and eligible participants attended three lab visits in total: a baseline visit, a Week 0 visit, and a Week 8 visit. A researcher worked individually with each participant, one at a time. At the baseline visit, participants were randomized into either a group who received the intervention workbook plus a wearable self-monitoring device group (WD), or a group who received only the intervention workbook (WO). Dietary intake was assessed by three multiple-pass 24-hour dietary recalls, both before and after the Week 0 and 8 visits. During the Week 0 and 8 visits, height was measured in duplicate using a digital wall-mounted stadiometer (SECA 240, Hamburg, Germany), rounding to 0.1 cm, and the average height of the two measurements was recorded. Weight was measured in duplicate using a digital scale (SECA 700, Hamburg, Germany), rounding to 0.1 kg, and the average of the two measurements was recorded. Participants were served an ad libitum test breakfast in the lab on a universal eating monitor (UEM), which measured food disappearance over time to provide a measure of eating rate (54). Participants were offered a choice of oatmeal flavors: maple brown sugar (491.08 grams, 819.6 kcalories, = 1.7 kcalories per gram) or cinnamon spice flavor (=497.1 grams, 845.6

kcalories, 1.7 kcalories per gram). This mixed macronutrient standardized test breakfast consisting of oatmeal enriched with protein powder and mixed with milk and butter to approximate a 50% carbohydrate, 15% protein and 30% fat meal as analyzed by the Food Processor SQL (ESHA Research, Salem, OR). Participants were instructed to eat as they normally would, until comfortably full. After the meal, participants completed the WREQ and 7-day Physical Activity Recall (PAR) under standardized laboratory conditions.

2.3. Intervention Workbook

All participants were provided with a workbook that offered education about reducing the number and energy density of bites, reducing ER, and increasing number of steps and overall physical activity. Techniques shared by the workbook to promote reduction of energy density included suggestions of low calorie, high volume foods, and reducing liquid calories, and suggestions for reducing eating rate included chewing food 20-30 times and putting utensil down between bites. Tips for increasing physical activity included walking on lunch breaks and parking the car further away from destination. The workbook was designed for participants to briefly focus on one topic per metric per week, and each week's topic was covered in 2-3 pages. The workbook wrapped up each week's topic by summarizing main points, offering 3-4 suggestions of new behaviors to practice over the next week. A space was also provided at the end of each week to record personal goals for the week, as well as a space to identify what went well and what was challenging. Participants were told that the workbook was to be followed on their own, and encouraged by weekly emails from the research team to keep up with each week in a timely manner. Topics covered within the workbook are listed in Table 2.

2.4. Eat Less, Move More (ELMM) Device

The Eat Less, Move More (ELMM) device is wrist-worn, and is capable of tracking bites by detection of a wrist-roll motion specific to eating (23). The device can also reflect ER as measured in seconds between bites (24), as well as the number of steps taken by the user. Participants who were randomized into the WD group were received the ELMM device and were provided with a demonstration on its use. They were shown how to turn the device on and off at the beginning and end of meals, and how to connect the device to a computer to upload their data.

2.5. The Weight Related Eating Questionnaire (WREQ)

The WREQ is a 16-item, four-factor questionnaire, and is a validated tool designed to assess theory-based aspects of eating behaviors of participants on four subscales: three items for routine restraint (RR), three items for compensatory restraint (CR), five items for susceptibility to external cues (SEC), and five items for emotional eating (EmE) (53). As specified by Schembre and colleagues (53), the two restraint subscales originate from one restraint scale, representing the dietary restraint theory, which describes the intentional restriction of energy intake to control weight (55). The susceptibility to external cues subscale represents the theory of externality, which describes a behavior of eating in response to external oro-sensory cues, regardless of internal signals of hunger or satiety (56). The emotional eating subscale is represented by the psychosomatic theory, and denotes eating in response to negative emotions (57). This tool was used to collect information about the eating behaviors of participants before and after the intervention.

2.6. Statistical Analysis

A power analysis using GPower 3.1 (58) indicated that a sample size of 60 was needed to detect a weight loss difference of 2.6 kg between groups. These estimations were derived from a previous study exploring the effects of podcast technology to promote weight loss (59). All statistical analyses were performed with SPSS version 24 (Statistical Package for Social Sciences, IBM-SPSS Inc., Armonk, New York). Descriptive statistics (means, standard deviations, frequencies and percentages) were used to summarize demographics, and all data were assessed for skewness and kurtosis. Outliers were identified from examination of boxplots. Three outliers were identified for Week 0 body weight, but all were high which would be expected for a weight loss intervention. One outlier was identified in the restraint subscale, but this value was within the range of the 0-5 scale and kept in for analyses. All data were found to be normally distributed without significant skewness or kurtosis. Independent *t* tests were used to identify between group differences in continuous variables, and chi square tests of homogeneity were used to identify between group differences in nominal variables at baseline. Repeated measures analysis of variance (ANOVA) determined between group differences in the primary outcome of body weight change. Two-by-two repeated measures multivariate analyses of variance determined between and within group differences in secondary outcomes: ER, EI and energy expenditure, as well as in tertiary outcomes, WREQ scores. For these tests, intention to treat analyses were run. At week 8, participants were grouped into weight loss (WL) and weight stable/gain (WSG) groups, as defined by any weight loss at all versus weight that remained exactly the same or increased. This was conducted as a completer's analysis, given last point carry-over nature of intent to treat analysis that would artificially increase the size of the stable weight participant group. A 2X2 repeated measures multivariate analysis of variance determined between and within group differences in the three WREQ subscales: restraint, susceptibility to external cues, and emotional eating. Correlations were run to assess associations between WREQ scores and body weight change. All statistical tests were two-tailed, and considered significant if p value was < 0.05.

4. Results

Participant characteristics at Week 0 and Week 8 are presented in Table 1. Seventy-two participants were enrolled in the study, and 13 participants (11 from experimental group, 2 from control group) withdrew. Reasons for withdrawal included busy schedules preventing completion of study (n=7), loss of the device (n=4), change of job away from campus (n=1), and return of the device by mail with a list of complaints about it (n=1). Participants were primarily women (65.3%), Caucasian (69%), had a mean age of 37.7 ± 15.3 and a mean BMI of 31.3 ± 3.2. At Week 0, there were no statistically significant differences between groups in age, weight, BMI, race, ethnicity, or previous use of self-monitoring wearable device technology.

Time by WO/WD group interaction results for primary and secondary outcomes are presented in Table 2. There was a strong main effect of time for the primary outcome variable of body weight, $F(1,70) = 9.6$, $p = 0.003$, partial $\eta^2 = 0.12$. There was no time by WO/WD group interaction on body weight, $F(1,70) = 0.7$, $p = 0.4$, partial $\eta^2 = 0.01$. There was no time by WO/WD group interaction on secondary outcomes of EI, ER, and PAR-EE, Wilks' $\Lambda = 0.96$, $F(3,61) = 0.74$; $p = 0.53$, partial $\eta^2 = 0.04$, but there was a significant main effect of time, Wilks' $\Lambda = 0.87$, $F(3,61) = 3.1$; $p = 0.035$, partial $\eta^2 = 0.13$. Follow-up univariate analyses showed a significant effect of time on EI, $F(1,63) = 4.8$, $p = 0.035$, partial $\eta^2 = 0.07$.

The 64 participants who completed the study were dichotomized into weight loss (WL) and weight stable/gain (WSG) groups (n=40 and 24, respectively). No significant effects of time, WL/WSG group, or time by WL/WSG group interaction were found in secondary outcomes of EI, ER and PAR-EE (time = Wilks' $\Lambda = 0.87$, $F(3,54) = 2.6$; $p = 0.06$, partial $\eta^2 = 0.127$; WL/WSG group = Wilks' $\Lambda = 0.96$, $F(3,54) = 0.90$; $p = 0.47$, partial $\eta^2 = 0.045$; time by WL/WSG group interaction = Wilks' $\Lambda = 0.95$, $F(3,54) = 1.0$; $p = 0.42$, partial $\eta^2 = 0.05$).

For the tertiary outcomes, eating behaviors as assessed by WREQ scores, results from an intent to treat 2X2 repeated measures multivariate analysis of variance between the WO/WD groups showed a significant effect of time on WREQ scores, Wilks' $\Lambda = 0.77$, $F(3,68) = 6.63$; $p = 0.001$, partial $\eta^2 = 0.23$. Scores from the RR and CR subscales were combined into one restraint (RES) subscale, which is appropriate per Schembre and colleagues (53). Post hoc univariate analyses showed there was a significant time effect on RES scores, $F(1,70) = 15.44$; $p < 0.001$, partial $\eta^2 = 0.18$, and

SEC scores, $F(1,70) = 6.56$; $p = 0.013$, partial $\eta^2 = 0.08$. A completer's analysis was run to examine results from a 2X2 repeated measures multivariate analysis of variance between the WL/WSG groups (n=40 and 24, respectively). There was a strong overall main effect of time on WREQ scores, Wilks' $\Lambda = 0.82$, $F(3,60) = 4.5$; $p = 0.007$, partial $\eta^2 = 0.18$. There was also a significant time by WL/WSG group effect, Wilks' $\Lambda = 0.87$, $F(3,60) = 3.05$; $p = 0.035$, partial $\eta^2 = 0.13$. Post hoc univariate analyses, illustrated in Figure 1, showed a significant main effect of time on RES scores, $F(1,62) = 9.93$; $p = 0.003$, partial $\eta^2 = 0.14$, and a significant time by WL/WSG group interaction effect on SEC, $F(1,62) = 8.31$; $p = 0.005$, partial $\eta^2 = 0.12$, but not on RES, $F(1,62) = 0.27$; $p = 0.61$, partial $\eta^2 = 0.004$, or on EmE, $F(1,62) = 1.3$; $p = 0.27$, partial $\eta^2 = 0.02$. There were no associations between RES scores or EmE scores and body weight change, but significant associations were seen between Week 0 SEC scores and body weight change ($r = -0.28$, $p = 0.017$), and between change in SEC scores and body weight change ($r = 0.36$, $p = 0.004$).

5. Discussion

This study was the first to apply a novel grouping of techniques relating to reducing EI through decreased number of bites, reducing ER, and increasing steps within a weight loss intervention, and found a significant time effect on weight loss. In addition, participants who rated themselves more vulnerable to giving into external eating cues at baseline had the most success with this unique weight loss approach. There was no added benefit of a wearable self-monitoring device to this intervention, as its presence did not further enhance the participants' weight loss; we saw statistically significant reductions in body weight over time in both groups.

We hypothesized that participants in the experimental group who used the ELMM device would lose more weight than those in the control group. While we did not see this result, there was a significant effect of time on weight change. A previous study compared the weight loss effects of the ELMM device with a Podcast-focused weight loss intervention (60). In that study, 81 adults were randomized into two types of dietary self-monitoring: one with the ELMM and one with a mobile app ; all participants received twice weekly Podcasts which delivered behavioral weight-loss information. After both three and six months, there was a significant time effect of weight loss in both groups; this finding is similar to the present study in that we also saw a significant time effect across both groups. However, our intervention was only two months in duration. In that study, at the six-month mark, there was a significant difference between groups, in that the mobile app group lost significantly more weight compared to the ELMM group. We saw no additional benefit of the ELMM device at the end of our two-month intervention, but it is worth considering that if the present study had continued for longer, it is possible that a significant difference in weight loss between groups may have been seen.

Another recent study by the same research group that investigated the use of self-monitoring of bites with the ELMM device in a 4-week weight loss intervention showed weight loss in a group of 12 participants with overweight or obesity (61). Results showed that use of the device was significantly correlated with weight loss (61). There were also improvements in weight management behaviors as measured by

Eating Behavior Inventory. However, it is difficult to know if the weight loss or behavior changes were the result of the device use, as there were multiple supports built into the study design; these included goal-setting, weekly challenges, biweekly podcasts, and four weekly one-hour educational sessions delivered by a registered dietitian who was experienced in weight loss training. In addition, the sample size of 12 participants was small, and the study design lacked a control group to compare between group differences. The present study enrolled a larger group of participants for a longer period of time, and was designed to allow the participants to follow a self-led workbook without additional support such as weekly counseling sessions and assistance with modification of goal setting. Our randomized design also allowed us to compare results from a group with the device against a group without it.

It is important to note that the overall average weight loss seen in the present study was less than other studies (59, 61). However, Gardner and colleagues also reported smaller weight changes in a recently published 12-month weight loss study in the *Journal of the American Medical Association (62)*. That study compared the effects of a low-fat versus low-carbohydrate diet in 609 adults, which resulted in a mean weight loss of 5.3 kg and 6.0 kg, respectively (average weekly weight loss was 0.22 kg) (62). A recent review of 60 group-based weight loss interventions showed an average 12-month loss of 3.4 kg, approximately 0.07 kg reduction per week (63). The results from those studies are similar to those of the present study, which resulted in an average weight loss of 0.10 kg/week.

It is possible that weight loss interventions that focus on eating behavior change results in smaller weight loss outcomes; evidence of this trend is demonstrated by a systematic review of mindfulness-based weight loss programs which demonstrated that the overall weight reduction was about 3.3%, compared to an average reduction of 4.7% from diet and exercise programs (64). However, at follow-up participants involved in mindfulness interventions continued with weight loss (average of 0.2%) while those in diet and exercise interventions actually regained weight (average of 0.4%) (64). These findings suggest two things: 1) that smaller amounts of weight loss have been seen in behavioral weight loss interventions; and 2) that a behavioral component that includes increasing mindfulness and awareness of physiological cues to eating is important in weight reduction, and may promote longer-term weight loss maintenance.

In the present study, a significant main effect of time was seen with reductions in the three main secondary outcomes, EI, ER, and energy expenditure; however, there was no main effect of WO/WD group or time by WO/WD group interaction. It is important to consider that the main effects of time in both the primary outcome variable of weight change, as well as in the three metrics of the intervention, EI, ER and energy expenditure; therefore, the intervention seemed to be effective across both groups. Additionally, post hoc follow-up tests showed that there was a significant effect of time on EI. Two of the key concepts constructed within the intervention workbook included information and strategies to reduce the size and number of bites, as well as to reduce eating rate, which may have contributed to the significant decrease in EI over time.

The present study offers new insight into eating behavior-related topics that may be effective in guiding weight loss education. Participants who scored higher in susceptibility to external cues significantly reduced their scores in this subscale at the end of the intervention. There was a strong time effect on RES and SEC scores, demonstrating significant increases in self-reported restraint and significant reductions in SEC scores post-intervention, as seen in other studies (65-68). Participants who lost weight had higher SEC scores at Week 0, and had significant reductions in these scores when compared to those with stable or increased weight at the end of the intervention. Additionally, significant associations were found between SEC scores and weight change, in that participants with higher Week 0 SEC scores lost more body weight, and participants with greater reductions in SEC scores lost significantly more weight. Individuals who are susceptible to external eating cues are more likely to eat regardless of internal signals of hunger and satiety; they are highly reactive to external stimuli such as the sight and smell of foods, and consume foods as a result of these environmental exposures (69).

Motivations to begin and end eating occasions can certainly differ among individuals, and can include variable reasons including hunger, emotion, motivation to control weight, and external eating cues (53). The presence of an obesogenic environment, in which there is a high frequency of exposure to eating cues that often focus on energy dense food items, can make it difficult to make healthful food decisions, particularly for those who have a high susceptibility to such cues (68); indeed, variability in weight status may be partially dependent on inter-individual response to external eating cues (70). Even in the presence of increased availability of health information and insight into the connection between diet and disease, obesity rates have continued to rise (71). Verhoeven and colleagues examined the effects of health warnings in participants in the absence of food-associated stimuli (72). In that study, while health warnings successfully changed the desire to eat unhealthy foods in the absence of food cues, when unhealthy food-associated stimuli were present, the exposure to health warnings were not effective and participants preferred the unhealthy food (72). A landmark study by Abratt and Goodey demonstrated that in a supermarket setting, 50% of the purchases were unplanned, and 67% of these were due to environmental cues such as retail displays (73). External eating has been associated with higher EI and consumption of energy-dense foods in young women (74). External eating has also been associated with increased self-reported EI in healthy weight women (75). Furthermore, individuals who are more likely to respond to eating cues from the external environment have a higher risk for consuming foods that may be less healthful (68, 76). In a study that sought to identify predictors of food cravings, in 124 normal weight adults, externality was shown to be the principal predictor of food cravings for a number of food groups, including fats, carbohydrates, and sweets; moreover, external eating predicted total food craving scores (68). Herman and Polivy (69, 77, 78) suggested that the impact of external food cues may be increased in individuals with obesity, as well as those experiencing hunger (69). Our intervention offered information relating to reducing bites, slowing down speed of eating, and increasing steps through eight weeks, which may contribute to an increased awareness of internal factors related to eating.

The nature of the content of our workbook involved increasing awareness of internal eating cues, including the identification of hunger sensation as well as satiety. The topics covered in the workbook included reducing bite count and bite frequency.

Even in the absence of a device that counts these metrics, the workbook encouraged an increased awareness of bites taken during meals and encouraged participants to chew each bite of food 20-30 times, put down the utensils in between bites, and encouraged longer pauses between bites. The workbook encouraged fewer, smaller bites, and increased nutrient density of foods, including reducing liquid calories and replacing high calorie snacks with fruit or vegetables. Additionally, the topics covered appetite awareness, and trying to listen to internal signals of hunger before eating, as well as stopping the meal when feeling comfortably satisfied. The increased awareness factor promoted by the intervention workbook, while perhaps not effective for other eating behaviors, may have fostered a decreased susceptibility to eating as a result of external cues from the environment.

There was also a significant main effect of time on dietary restraint scores, which is not unusual in a weight loss intervention. Historically, dietary restraint was perceived to be a negative consequence of dieting for weight reduction that potentially promoted eating pathology, or symptoms of disordered eating (79, 80). However, dietary restraint has also been viewed as an eating behavior that may contribute to favorable outcomes, including weight management (81-83). A secondary data analysis of an 18-week weight loss study identified cognitive dietary restraint as the most robust predictor of weight loss (84). In another study examining a group of long-term weight-loss maintainers, higher dietary restraint was found to be one of the strongest discriminators that differentiated between weight-loss maintainers and two other obese weight loss treatment-seeking groups (82). We saw a significant time effect of increased dietary restraint scores as measured by the WREQ, demonstrating that there may be a possible effect from the intervention on this eating behavior.

It may be beneficial to try to identify those who may benefit most from the intervention used in the present study. In a study that aimed to explore eating behaviors in terms of personality traits, Elfhag and Morey sought to identify predictors of eating behaviors (76). Results showed that impulsiveness explained 28% of the variance in external eating, and the tendency to respond to attractive external food stimuli was related to lack of inhibition in relenting to these stimuli (76). Another study found a positive correlation between impulsivity and external eating in individuals with overweight or obesity (85). Our intervention included increasing awareness of inhibitory internal signals such as fullness and satiety. Increased awareness of these factors may be helpful in aiding individuals who are prone to external eating to respond in more controlled manner, because these individuals may be more responsive to this type of intervention. We saw no added benefit of self-monitoring through the use of a wearable device, but the provision of education and guidance relating to bite count, ER and physical activity in the form of steps taken may have been effective in raising awareness of internal cues and reducing susceptibility to external cues. Future weight loss studies may consider this type of intervention for participants who are more prone to eating in response to external cues that are independent of internal hunger and satiety indicators.

There are several strengths to this study such as the randomization to the workbook only or the workbook plus device groups. Strengths also include the use of a validated questionnaire to assess eating behaviors (53), and the low attrition rate of

<17% (<11% once intervention began), which is lower than the 25% attrition rate encountered by most weight loss studies of this duration (86). Future directions may consider weight loss interventions focused on increasing awareness of internal hunger and satiety cues within a bites, ER and steps-based program in a sample of individuals with obesity from a more diverse background. Limitations to this study include the lack of ability to assess compliance to using the workbook. However, we sought to reduce researcher involvement in providing education around reducing ER in this study, to increase independence of the participants in following a more scalable approach to weight loss compared to one-on-one and small group coaching done previously in our lab (47, 48). Another limitation is the predominantly Caucasian sample, which may make it difficult to generalize to other populations. However, our sample encompassed a wide range of ages from 18 – 60 years, which makes the findings more generalizable to different adult age groups. This study recruited overweight and obese subjects and found new associations between external eating behaviors and weight loss success, which adds new information to the existing literature.

5. Conclusion

In summary, our results provide the first application of a weight loss intervention focused on a unique combination of three metrics: decreasing the size and number of bites; reducing ER; and increasing physical activity through increasing steps. This intervention was found to be effective for weight loss. A weight-related eating behavior, specifically, susceptibility to external cues, was associated with weight loss success. Individuals who are prone to being more vulnerable to environmental and external eating cues may benefit from a weight loss intervention focused on reducing bites and ER, increasing steps, and increasing awareness of internal satiety signals. Future directions for weight loss research might include the incorporation of a longer-term intervention focused on reducing bites and ER and increasing steps, as well as raising awareness of internal eating cues, within a more diverse sample to promote weight loss achievement.

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Contributors

Dr. Kathleen Melanson, Dr. Geoffrey Greene and Jacqueline Beatty were responsible for design of the experiment. Dr. Kathleen Melanson and Dr. Geoffrey Greene proofread the manuscript and provided valuable feedback. Dr. Kathleen Melanson developed the intervention workbook from several years of research in her laboratory. Nicole Everett and Jacqueline Beatty assisted with its development, and Dr. Geoffrey Greene and Dr. Bryan Blissmer provided valuable feedback on the intervention workbook. Jacqueline Beatty supervised the collection of data, analyzed the data, and wrote the manuscript.

Conflict of interest

There are no conflicts of interest.

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Chapter Two Tables and Figures

Figure 1. Outcomes, Hypotheses and Data Collection Points.

Outcomes	Hypotheses	Week 0 and Week 8 Data Collection
PRIMARY: Body weight	Participants in the WD group will lose more weight than those in the WO group	Week 0 and Week 8 lab visits
SECONDARY: EI, ER, and EE	Participants in WD group will increase EI and ER and decrease EE more than WO group	EI: 2X24-hour dietary recalls preceding Week 0 and Week 8, plus 1 from lab visits ER: Week 0 and Week 8 UEM-measured test meal EE: 7-day PAR Week 0 and Week 8 lab visits
TERTIARY: Eating behaviors as measured by WREQ scores	Participants in the WD group will have greater improvements in WREQ scores than those in the WO group	WREQ scores Week 0 and Week 8 lab visits

Table 1. Participant characteristics.

Characteristic	WD	WO	*P* value
	(n=37)	(n= 35)	
Mean±SD			
Age, years	36.5±16.1	38.9±14.7	0.51
BMI, kg/m^2	31.2±3.5	31.5±3.0	0.69
Body fat percent (%)	36.8±8.6	38.4±8.5	0.42
Waist Circumference (cm)	103.7	103.1	0.80
Sex, n(%)			0.75
Male	14(37.8)	11(31.4)	
Female	23(62.2)	24(68.6)	
Ethnicity, n(%)			0.60
Hispanic or Latino	2(5.4)	4(11.4)	
Not Hispanic or Latino	29(78.4)	25(71.4)	
No answer	5(16.2)	6(17.1)	
Race, n(%)			0.34
American Indian or Alaskan Native	0	1(2.9)	
Asian	6(16.2)	3(8.6)	
Black or African American	2(5.4)	5(14.3)	
White	26(70.3)	23(65.7)	
Other	1(2.7)	2(5.7)	
No answer	2(5.4)	1(2.9)	
Previous Use of Other Self-Monitoring Device			
Previous Use: Yes n(%)	5(13.5)	12(34.3)	0.32
Frequency of Use: n(%)			0.08
None	31(86.1)	23(65.7)	
1-2 days per week	0	0	
3-4 days per week	1(2.8)	0	
5-6 days per week	1(2.8)	2(5.7)	
Daily	3(8.3)	10(28.6)	

WD = workbook plus device group; WO = workbook only group; BMI = body mass index; differences between age, BMI, body fat percent and waist circumference were analyzed by independent *t* tests; differences between sex, ethnicity, race, and previous use of other self-monitoring devices were analyzed by chi-square tests of independence.

Table 2. Weight loss intervention workbook topics.

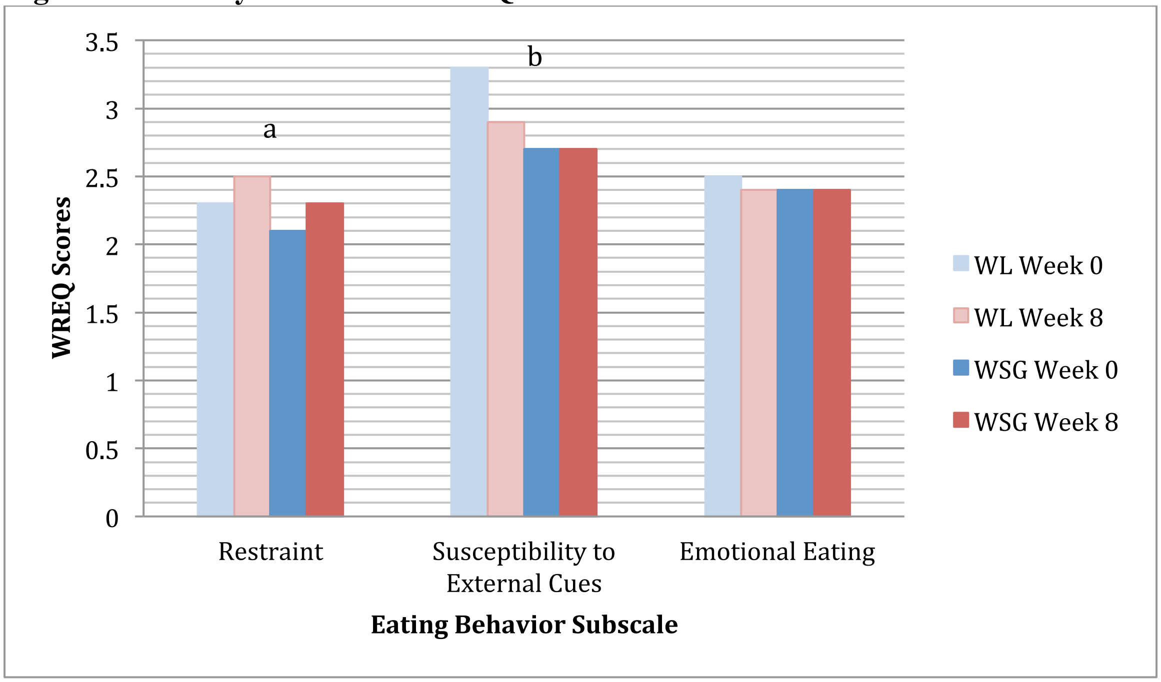
Week	**Topics**
1	Negative energy balance: increasing physical activity; reducing bite count and bite frequency; goal setting
2	Tips for increasing steps; reducing bite size & bite frequency
3	Increasing movement; lowering energy density of foods to decrease kcals/bite
4	Adding new activities; adding long interbite pauses & appetite awareness
5	Overcoming exercise barriers; reducing liquid kcals, lowering kcals per bite (size/density)
6	Incorporating exercise in routines; fewer, slower, smaller bites
7	Less sedentary behavior; overcoming barriers to slower eating and fewer smaller bites
8	Review of concepts and plans for maintenance and continued progress

Table 3. Primary (weight) and secondary (energy intake, eating rate, and energy expenditure) outcome results.

All values in Means ± SD	**WD (n=37)**		**WO (n=35)**		***Time Effect p Value*** **(partial η^2)**	***Time by Group Interaction*** ***p*** **value (partial η^2)**
	Week 0	Week 8	Week 0	Week 8		
Primary Outcome:						
Weight (kg)	88.9±14.2	87.9±14.7	89.6±14.7	89.0±14.7	0.003* (0.12##)	0.40 (0.01#)
Secondary Outcomes:					0.035* (0.13##)	0.53 (0.04#)
Energy Intake (kcals/day)	2012.6±630	1781.3±660	1905.3±601	1844.5±539		
Eating Rate (grams/minute)	31.6±14.1	28.3±15.4	30.5±12.7	27.7±15.1		
Energy Expenditure (kcals/day)	1419.5±564	1607.8±1097	1481.4±634	1537.8±504		

WD = workbook plus device group; WO = workbook only group; differences between groups in primary outcome were analyzed by repeated measured ANOVA, and differences between groups in secondary outcomes were analyzed by repeated measured MANOVA. * = significant *p* value; # = partial eta squared indicating small effect size; ## = partial eta squared indicating large effect size

Figure 2. Tertiary Outcomes: WREQ Scores.



WREQ = Weight related eating questionnaire. Follow-up univariate analyses from significant repeated measures MANOVA assessed group differences in weight-related eating behavior between participants who lost weight (WL) compared to those with stable weight or weight gain (WSG). [a] Significant time effect on restraint scores, $p < .05$ level; [b] Significant time by WL/WSG group interaction on susceptibility to external cues, $p < 0.01$.

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CHAPTER THREE

"Relationships between energy expenditure, body fat, and respiratory exchange ratio in adults with obesity after a moderate 8-week weight loss intervention"

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CHAPTER THREE

Relationships between energy expenditure, body fat, and respiratory exchange ratio in adults with obesity after a moderate 8-week weight loss intervention

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Summary

Objectives: Maintaining weight loss is difficult, in part due to changes in resting metabolic rate (RMR) and substrate oxidation that accompany weight reduction. To date, most research has examined RMR and substrate oxidation after moderate to large body weight changes. In reality, many individuals with obesity attempt weight loss themselves, resulting in only minor weight changes. This study examined RMR and substrate oxidation (as reflected by respiratory exchange ratio, RER) within an 8-week, self-led weight loss intervention.

Methods: As an adjunct study to an eight-week weight loss intervention, changes in RMR (primary outcome), and RER, body fat, and estimated energy expenditure (secondary outcomes) were examined. Twenty-two adults (13 females; age 34.6±16.5 years; BMI 32.0±4.3 kg/m^2) received a self-directed workbook focused on reducing bites and eating rate while increasing steps. Of these, 12 were randomized to additionally receive a wrist-worn device for self-monitoring of the behaviors. At Weeks 0 and 8, RMR, RER (both by indirect calorimetry), body fat percent (BodPod), and estimated energy expenditure (7-day Physical Activity Recall, PAR-EE) were collected. For analysis of primary and secondary outcomes, participants were pooled, and paired t-tests examined changes over time. Correlations explored associations among these variables. Participants were then dichotomized into a weight loss group (WL) or a weight stable/gainers group (WSG), and exploratory outcomes assessing eating behaviors as measured by the Intuitive Eating Scale (IES-2) were examined by a 2X2 repeated measured MANOVA, with device group as a covariate.

Results: Pre-post changes in RMR (+14.7±108.8 kcals/day), RER (+0.14±0.05), body fat percent (-0.77±10.5%), and PAR-EE (+180±584 kcals/day) were not statistically significant. A significant, moderate negative correlation was found between week 8 PAR-EE (mean = 1652±568 kcals/day) and week 8 RER (0.85±0.04, r =-0.433, p =0.04). A significant, moderate negative association was also found between week 8 body fat percent change (-0.49±1.78%) and RER change (0.014 ± 0.052, r = -0.434, p = 0.044). Exploratory outcome results showed a significant time by WL vs. WSG group effect of IES-2 subscale scores (Wilks' $\Lambda = 0.47$, $F(4,12) = 3.4$; $p = 0.045$, partial $\eta^2 = 0.53$), and follow-up univariate analyses showed a significant time by group effect, with those in the WL group self-reporting significantly higher scores in the Eating for Physical Reasons rather than Emotional Reasons (EPR) subscale ($F(1,15) = 9.0$; $p = 0.009$, partial $\eta^2 = 0.38$).

Conclusions: Participants with increased physical activity after an 8-week weight loss intervention tended to have higher fasting fat oxidation. These data suggest that even with minor changes, increased energy expended in physical activity may be associated with greater fat oxidation, which may favor weight loss maintenance. Higher change in body fat was associated with higher RER change; as change in body fat percent increased, change in RER decreased, which supports previous findings in the literature. Exploratory findings suggest that participants who improved in eating behavior related to eating for physical over emotional reasons, were more successful in weight loss within a self-led weight loss intervention focused on reducing bites and eating rate..

Keywords: Energy expenditure, indirect calorimetry, fat oxidation

1. Introduction

Obesity is prevalent, with current levels reaching 35% of the United States population, and is a significant contributor to chronic disease (1, 2). Achieving even a modest weight loss of 5% may help reduce many of the risk factors associated with this condition (37, 38). As critical as the achievement of weight loss to reduce obesity and its associated comorbidities is, consideration must be given to the importance of weight maintenance to achieve the positive health improvements attributed to weight reduction. A significant barrier to the ability to maintain weight loss is adaptive thermogenesis, otherwise known as metabolic adaptation. Metabolic adaptation is defined as a reduction in resting metabolic rate (RMR) as a result of weight loss, which is greater than would be expected based on the amount of weight lost (87, 88). This phenomenon has been well documented in the literature; in the presence of a negative energy balance, RMR decreases further than would be expected from reductions in body mass and changes in body composition (87-89). Furthermore, the existence of this state likely contributes to the difficulty of individuals with obesity to further reduce weight and maintain the loss (87, 90). The literature has demonstrated that this adaptation takes place with the preservation of fat free mass, and is persistent over long periods of time, even up to six years after weight reduction (91).

In addition to the effects of a reduced metabolic rate on weight loss maintenance (88, 89, 92), lower levels of fat oxidation can also impede an individual's ability to maintain weight loss (87, 90, 93). Changes in body weight, particularly in fat mass, have been shown to affect substrate oxidation, as measured by respiratory exchange ratio (RER); however, the literature examining RER changes in weight loss have shown conflicting results (94-97). A cross-sectional study of 106 women with obesity who maintained a stable weight showed that body fat mass was positively and significantly correlated with fat oxidation (94). Additionally, in a prospective study of a subset of 24 women from that study, fat oxidation decreased by an average of 42% after weight reduction from 135% to 112% of reference body weight, of which 77% of the weight lost was fat mass (94). Work done more recently has demonstrated increased fat oxidation after weight reduction. Participants without obesity who completed an alternate day fasting program lost 2.5% of their initial body weight and also had reduced fasting carbohydrate oxidation and increased fat oxidation (96). In a weight loss trial in which overweight young women who were randomized into an intermittent vs. continuous energy restricted diet, both groups lost weight (~12.5%, of which ~5.3% was fat loss), and had a subsequent reduction in RER, reflecting increased fat oxidation (97). Furthermore, changes in substrate oxidation have also been identified as a predictor of weight gain (98). In a landmark study from 1990 in 152 non-diabetic Pima Indians, lower fat oxidation rates were associated with increases in weight, independent of energy expenditure; participants with higher 24 hour RER were found to be 2.5 times more likely to gain weight than participants with lower RER (95).

Resting metabolic rate decreases with weight reduction as a result of both fat and lean body mass losses, and many of the previous studies that have examined metabolic effects of weight reduction have done so after moderate to large weight losses (88, 91, 99, 100). One well-known study was conducted with 16 participants who were enrolled in an intensive weight loss program that was telecast on television

(99); in this study, participants lost an average of 39% of their usual body weight over 30 weeks, which is a much higher amount of weight than an average individual might require, attempt or experience. Post-weight loss RMR relative to type of diet was examined in a 16-week weight loss intervention that compared low carbohydrate with low fat diets in 45 females with obesity; the mean weight loss was over 16% with a low carbohydrate diet and 8.7% with a low fat diet (100). Landmark work exploring the effects of weight change on RMR induced a 10-20% weight reduction in 18 participants with obesity and in 23 participants who had never had obesity (88); additionally, from that study, a more recent secondary data analysis was published examining the metabolic adaptation of 17 of those adults with obesity following the 10% and 20% weight reduction (101). These studies collectively demonstrate the relatively large weight loss in the literature examining post-weight loss RMR.

Such weight loss interventions or results are not typical; however, to date, much of the research has examined RMR and substrate oxidation after moderate to large body weight changes (99, 102). In reality, most individuals attempting weight loss experience only minor behavioral and weight modifications; therefore it is important to consider research based on minor changes. A recent study published in *Journal of the American Medical Association* presented a 12-month weight loss study that compared the effects of a low-fat versus low-carbohydrate diet in 609 adults, which resulted in a mean weight loss of 5.3 kg and 6.0 kg, respectively (average weekly weight loss was 0.22 kg) (62). A recent review of 60 group-based weight loss interventions showed an average 12-month loss of 3.4 kg, approximately 0.07 kg reduction per week (63). Obtaining information pertaining to RMR and substrate oxidation following weight loss interventions that produce smaller weight changes may be beneficial.

Moreover, eighty-nine percent of individuals who are registered with the National Weight Control Registry have reported using both diet and physical activity to achieve their weight loss goals, and nearly 47% of these have reported losing weight entirely on their own (103). Therefore we sought to collect information relating to RMR within an eight week, accessible, self-led weight loss intervention from which we expected more moderate changes. The purpose of this study was to examine changes in RMR within a weight loss intervention that included a self-led workbook, with or without a wearable self-monitoring device that aids in tracking dietary intake and physical activity through bite and step counting, respectively. Secondary outcomes included examining changes in substrate oxidation as measured by RER, body fat percent, and energy expenditure as estimated by the 7-day Physical Activity Recall. Exploratory outcomes included examination of eating behaviors as measured by the Intuitive Eating Scale-2 (IES-2) as they relate to weight loss as a result of the intervention.

2. Methods and Materials

2.1. Study Design and Participants

This study was an adjunct to an eight-week weight loss intervention. Seventy-seven adults were recruited to take part in the main study, details of which have been recorded elsewhere (104). Briefly, the last 22 adults were recruited to participate in an eight-week intervention, which required three individualized laboratory visits, plus two additional visits for the purposes of metabolic measurement. Non-smoking participants with overweight or obesity (body mass index [BMI] = 25.0 – 37.0 kg/m^2) between the ages of 18 and 60 years who were interested in losing weight were recruited from July 2016 – June 2017 from the University of Rhode Island (URI) campus in Kingston, RI and its surrounding areas to take part in a randomized weight loss trial. In order to participate in the study, participants had to be free from metabolic disease or conditions that may impact their appetite, including cancer, diabetes, adrenal disease, unmanaged thyroid disease, or eating disorders. Participants were not pregnant or lactating and were not taking any medications that may affect appetite. Participants provided informed written consent to participate in the study, which was approved by the University of Rhode Island's Institutional Review Board.

2.3. Procedures

Participants were screened by phone, and eligible participants were randomized into one of two groups, workbook only (WO) or workbook plus device (WD), before coming to the first laboratory visit. All participants received a weight loss workbook focused on reducing bites and eating rate and increasing steps, and the WD group also received a wearable self-monitoring device. Participants attended three lab visits in total: a baseline visit, a Week 0 visit, and a Week 8 visit. Lab visits were structured so that one researcher worked with one participant individually. For those who also took part in the current study (n=22), two additional lab visits were required and followed directly after the Week 0 and Week 8 visits by 1-2 days. All participants regardless of group assignment received the weight loss intervention during the Week

0 visit, which was a workbook that focused on three metrics to aid in weight loss: reducing the number of bites taken each day, reducing eating rate, and increasing the number of steps.

2.3.1 Eat Less, Move More (ELMM) Device

The ELMM device is wrist-worn and is capable of tracking eating rate as measured in seconds between bites, by time stamp and detection of a wrist-roll motion specific to eating (23). This device also measures the number of bites taken by the user when the user presses a button to turn the device into bite count mode, and stops counting bites when the user presses the same button to turn off the bite count mode (23, 25). The device also automatically tracks the number of steps taken by the user (61). Participants randomized into the WD were educated on the use and application of the ELMM device and were provided with a demonstration of how to download the device software onto their computers, and how to open the software to read goal setting pages and data.

2.3.2. Questionnaires

7-Day Physical Activity Recall (PAR): All participants were individually interviewed about the type, intensity, frequency and duration of physical activity that they had participated in during the previous seven days using the validated 7-Day PAR (105, 106). This allows researchers to compare information about the level of physical activity participants are participating in before and after the intervention. The *Intuitive Eating Scale* (IES-2) was used to assess baseline and post intervention feelings towards eating, with a focus on internal cues for eating. The IES-2 is a validated four-subscale tool measuring degree of adherence to intuitive eating principles; subscales include Unconditional Permission to Eat, Eating for Physical rather than Emotional Reasons, Reliance on Internal Hunger/Satiety Cues, and Body-Food Choice Congruence (107, 108).

2.3.3. Measurement of Anthropometrics

At the Week 0 and Week 8 visits, height was measured in duplicate using a digital wall-mounted stadiometer (SECA 240, Hamburg, Germany), rounding to 0.1 cm, and the average height of the two measurements was recorded. Weight was measured in duplicate using a digital scale (SECA 700, Hamburg, Germany), rounding to 0.1 kg, and the average of the two measurements was recorded. Body composition was measured by air displacement plethysmography (BodPod, Life Measurement Instruments, Concord, CA) following standardized procedures (26, 27).

2.3.4. Measurement of RMR

Each participant came into the lab after a 10-hour fast the one to two days after the previously described Week 0 and 8 visits. Upon entering the lab, the researcher confirmed fasting state and asked the participant to remove shoes and any excess bulky clothing other than light street clothing. Prior to indirect calorimetry testing in a climate-controlled room, the participant was first weighed, to account for any changes since the previous day or overnight. The participant was then asked to lie in a supine, elevated position on the laboratory bed for a 30-minute pre-test resting period. Flow rate and gas calibrations were performed using two calibration tanks containing different CO_2 and O_2 concentrations, as directed by the manufacturer's instructions (Vmax Encore 29, Care Fusion, Palm Springs, CA). A ventilated hood was placed over the participant's head for a 45-minute measurement of RMR and RER (VCO_2/VO_2) by ventilated hood indirect calorimetry. Each participant was asked to refrain from sleeping, writing, or using their phones in any way, and was monitored closely to assure compliance with the protocol. Throughout this time period, acquired VO_2 and CO_2 were converted into RMR by the indirect calorimeter using the Weir equation (109). Upon completion of measurements, participants received a printed copy of their RMR results, and were offered a choice of two different flavored breakfast bars and choice of juice box or water before leaving the lab.

2.3.5. Statistical Analysis

For the purposes of this study, all participants were pooled to examine changes in the primary outcome of RMR and secondary outcomes of RER, body fat percent, and PAR-EE. This is because no differences were seen in any outcomes between WD and WO. Descriptive statistics were used to summarize demographics using means, standard deviations, and frequencies. All data were examined for skewness and kurtosis and found to be normally distributed. Two outliers were identified in this data set upon examination by stem-and-leaf diagrams and boxplots (one in Week 8 RMR, and one in Week 8 PAR-EE), and they were kept in the analyses as further examination revealed both of these data points to be within an acceptable range; the Week 8 RMR data point was valid and similar to that participant's predicted RMR, and the Week 8 PAR-EE data point was appropriately reported from a physically active participant. An intent to treat analysis was run with the assumption that the participants who dropped out had no change in outcomes. Paired *t*-tests were used to examine change over time in the primary outcome, RMR, as well as in secondary outcomes, RER, body fat percent, and PAR-EE in all participants. Correlations explored associations among these variables. Participants were then dichotomized into a weight loss group (WL) or a weight stable/gainers group (WSG), and a completer's analysis was run to examine exploratory outcomes of assessing eating behaviors as measured by four subscales from the IES-2, with a 2X2 repeated measured MANCOVA, with device group as a covariate.

In order to create a backward linear regression model to predict RMR in this participant pool, baseline data were used to determine if a regression model would be a good fit for the data (110). This was done based on previous literature seeking the creation of a linear regression model to predict RMR based on study-specific data sets (89, 111). A least-squares best-fit model was generated to determine RMR based on age, sex, lean body mass (LBM), and fat mass (FM). The model showed that these four independent variables were a statistically significantly better fit to the data than the mean model ($F_{4,95} = 26.43$, $p<0.001$).

$$\text{RMR (kcalories/day)} =$$

$$738.33 - (166.023 \times \text{sex}) - (0.738 \times \text{age}) + (15.872 \times \text{LBM}) + (8.236 \times \text{FM})$$

R^2 for the overall model was 0.86, with an adjusted R^2 of 0.83, demonstrating that 83% of the proportion of variance in predicted RMR could be explained by age, sex, LBM and FM. Therefore this prediction equation was used to estimate predicted RMR based on age, sex, lean body mass and fat mass.

Metabolic adaptation was defined as the difference between predicted RMR as calculated based on the least squares linear regression equation, and measured RMR by indirect calorimetry (92):

$$\text{Metabolic Adaptation} = \text{Post intervention predicted RMR} - \text{Post intervention measured RMR}$$

3. Results

In total, 22 participants (13 female, 34.6±16.5 years, 32.0±4.3 kg/m^2) were included in the primary and secondary outcome analyses. Three participants from the experimental group withdrew, and 19 completed the intervention. Reasons for withdrawal were: finding the device uncomfortable to wear (n=1); losing the device (n=1); and dropping out, later returning the device, which had been damaged (n=1). Baseline characteristics at Week 0 are displayed in Table 1.

Paired *t*-test results demonstrating changes in predicted RMR, measured RMR and metabolic adaptation are presented in Table 2. There were no statistically significant differences over time. Pre-post changes in secondary outcomes of RER (+0.14±0.05), body fat percent (-0.77±10.5%), PAR-EE (+180.1±584.0 kcals/day), were also not significant. Significant associations relating to these secondary outcomes are presented in Figures 1 and 2: Figure 1 depicts the association between physical activity energy expenditure as estimated by the 7-day PAR and RER; a significant, moderate negative correlation was found between week 8 PAR-EE (mean = 1651.7±568.7 kcals/day) and week 8 RER (0.85 ± 0.04, r = -0.433, p = 0.04). Figure 2 shows a significant, moderate negative association between week 8 body fat percent change (-0.49±1.78%) and week 8 RER change (0.014±0.052, r =-0.434, p =0.04).

A completer's analysis was run to examine exploratory outcome results, which are illustrated in Figure 3. After dichotomization into a weight loss (WL) group (n = 13; mean age = 35.8±16.1 years; mean weight change = -2.0±1.3 kg; mean body fat percent change = -1.5±1.2%) or a weight stable/gainers (WSG) group (n = 6; mean age = 34.0±19.1 years; mean weight change = +1.7±1.1 kg; mean body fat percent change = +1.4±1.6%), a significant time by group interaction of IES-2 subscale scores was found (Wilks' Λ = 0.47, $F(4,12)$ = 3.4; p = 0.045, partial η^2 = 0.53). Follow-up univariate analyses showed a strong time by group interaction of Eating for Physical Reasons rather than Emotional Reasons (EPR) subscale ($F(1,15)$ = 9.0; p = 0.009, partial η^2 = 0.38).

4. Discussion

Results from this study in adults with overweight and obesity demonstrated a significant, positive association between energy expended from physical activity and increased resting fat oxidation. Even with this modest, self-led intervention, higher levels of energy expended through physical activity were associated with reduced Week 8 RER, or higher levels of fat oxidation. Key features of the present study include the measurement of RMR by indirect calorimetry after an 8-week weight loss intervention that provided guidance through a distinctive combination of principles including reducing bites and eating rate while increasing physical activity through steps. Adding to the uniqueness of the intervention, a focus on increasing awareness to internal vs. external eating cues contributed to a reduction of EPR subscale scores, suggesting that participants who were able to reduce these scores were more successful in weight loss than those without measurable change in this subscale.

Reduced fasting RER after an 8-week behavioral intervention is important because increased fat oxidation is associated with lower risk of weight gain over time (95). In a landmark study examining the relationship between fat oxidation and risk for weight gain (95), 24-hour RERs were measured in 152 non-diabetic Pima Indians, representative of a population with a high prevalence of obesity and diabetes (112). Participants were admitted into a metabolic ward and fed a weight-maintenance diet for 7 days prior to RER measurement in a respiratory chamber. One hundred eleven participants returned to the metabolic ward for follow-up an average of 25 months later, and were tested again. Results showed that 24-hour RER was associated with body weight and fat mass changes; participants with a higher RER, representing lower fat oxidation, were found to be at 2.5 times higher risk for weight gain of ≥ 5 kg body weight when compared to participants with lower RER (95). Moreover, this increased risk was independent of 24-hour energy expenditure.

The association between physical activity energy expenditure at the end of the intervention and reduced RER (increased fat oxidation) is noteworthy also because kcalories per day expended as estimated by the PAR is representative of the estimated amount of energy being expended at the end of the weight loss intervention. In the previous literature, physical activity during the active weight loss period, and weight regain after the intervention, have been correlated. Wang and colleagues (113), studied 34 women with overweight or obesity who lost significant amounts of body weight, body fat percent, and reductions in RMR and physical activity energy expenditure. Compared to those who remained active throughout the weight loss period, participants who had declining levels of physical activity during the weight reduction time period experienced greater weight regain during follow-up at 6 months and 12 months (113).

In another study, 116 adults with severe obesity underwent a weight loss intervention with diet alone or diet plus physical activity (114). Results of that study demonstrated that there was a positive association between increased levels of physical activity and maintenance of weight loss 7-12 months later (114). Results from these studies suggest that remaining physically active can help prevent weight regain, and supports recommendations to engage in physical activity for weight management (115). The National Weight Control Registry, established in 1994, is an archive of more than 4,000 adults who have successfully lost 30 pounds or more and have maintained this weight loss for a minimum of one year (103). One characteristic of these individuals is that they have relatively high levels of physical activity, equating to approximately one hour per day of moderate activity (such as brisk walking) (18). In our study, higher physical activity at the end of the intervention was associated with increased fat oxidation, which as noted above has been associated with reduced risk of weight gain (95).

Significant associations were also found between body fat percent change and RER change. A significant, negative correlation was seen; higher changes in body fat percent were associated with lower RER change. Because mean body percent change was -0.77%, and mean RER change +0.14, greater reductions in body fat percent were associated with less increase in RER, or more tendency to stay closer to fat oxidation. These findings support previous literature that has shown decreased fat oxidation with fat loss; in a prospective study in which 24 postmenopausal women underwent a weight reduction from 135% to 112% of reference body weight, of which 77% of the weight lost was fat mass, fat oxidation decreased by an average of 42% (94).

However, other studies have published contrary findings. Coutino and colleagues demonstrated a significant decrease in fasting RER (increased fat oxidation) in 35 adults with obesity who were randomized into either a continuous calorie restriction or an intermittent energy restriction group (97). Both groups lost similar amounts of body weight and body fat percent, and both groups had significant reductions in RER suggesting increased fasting fat oxidation (97). In another study, 16 men and women without obesity underwent a three-week intermittent fasting weight loss intervention (96). Two RER measurements were taken after three weeks: one after a habitual intake day, in which the RER remained similar to baseline, and one after an intermittent fasting day, in which participants were energy restricted; this RER measurement was decreased, suggesting movement toward fat oxidation (97). However, this RER may have been affected by the energy restriction the previous day; additionally, the latter study was done in participants with a healthier weight, and both of these studies were done in interventions that involved alternate day or intermittent fasting days. More research is needed in this area to establish how different weight loss approaches may be associated with reduced RER and increased fat oxidation.

The findings from the present study are meaningful, because it is important to understand what body weight and body fat percent changes are related to changes in RER; in early studies examining associations between substrate oxidation and weight, an increased RER (decreased fat oxidation) has been associated with increased weight gain (95), and higher RER has been shown to be a predictor of weight gain, independent of low RMR (116). Reduced metabolic rate as a result of weight loss and energy restriction (88, 89, 92), as well as lower levels of fat oxidation, can impede an individual's ability to maintain weight loss (87, 90, 93). In the present study, no significant changes were seen in measured RMR. There were also no significant changes in metabolic adaptation. There may be a few reasons that we did not detect significant changes in these measures. First, the amount of weight lost was fairly minimal over the eight weeks (-0.72±2.0 kg), which may be a reason there was not a significant change in RMR or metabolic adaptation, which typically accompanies larger weight reduction (88). Additionally, there was significant variability in the metabolic adaptation values: Week 0 = 0.02±105.5 kcalories/day, and Week 8 =

18.7±107.7 kcalories/day; these large standard deviations relative to their respective mean values show great between-participant variability. It is also possible that with the slight increases in physical activity, the reduction in RMR may have been minimized; indeed, while many weight loss studies show reduced measured RMR (88, 89, 100, 117), the present study showed a mean increase in RMR of 15 kcalories/day, and while this increase was not statistically significant, it was consistent with the increase in PAR-estimated energy expenditure.

Exploratory analyses showed that participants with greatest improvement in EPR scores were more successful in achieving weight loss when compared to those who did not change or those with a reduced score in this category. This eating behavior is a construct of the IES-2: its questions measure how well an individual is able to respond to physical symptoms of hunger as opposed to eating as a result of a specific negative emotion such as sadness, loneliness, depression, or boredom (118). The weight loss intervention workbook from the main study was centered on reducing bites, eating more slowly, and increasing awareness of physiological symptoms of hunger. The workbook encouraged eating in response to hunger as opposed to external eating cues. One example of this is the encouragement to eat only when hungry, not according to the clock or previously established habits. Previous literature has shown that women who tend to eat more for physical reasons over emotional reasons are less likely to binge eat and less likely to be preoccupied with food (119), which are behaviors that have been associated with weight gain (120, 121).

The improved EPR score in those who were successful (as measured by weight loss) in the intervention is noteworthy, because previous literature has established that individuals can develop maladaptive eating behaviors, such as increased emotional eating, as a result of weight loss interventions that require energy restriction (122, 123). This result may set the stage for weight loss/weight regain cycling patterns, as a result of strict dieting and inadequate consumption, establishing negative eating behaviors, and resultant weight regain. The workbook intervention from this study instead focused on positive behavioral adjustments (examples include replace one energy dense dessert with a fruit or vegetable; avoid eating while watching television or being distracted in any way; and slowing down eating even more when sensing fullness). By focusing weight loss education on more intuitive eating behaviors and encouraging awareness of physical signs of hunger and satiety, the development of negative eating behaviors can potentially be avoided and replaced. Similar intuitive eating strategy-based interventions focusing on positive eating behaviors have led to reduction of depressive symptoms (124, 125) and improved physical health (124, 126).

Limitations to this study include a lack of post-intervention weight stabilization period as implemented by previous studies examining RMR following large weight losses (88); however, the weight reduction in the present study was small, which suggests a reduced need for such a stabilization period. Another limitation is the predominantly Caucasian sample, which may make it difficult to generalize to other populations. However, our sample encompassed a wide range of ages from 18 – 60, which makes the findings more generalizable to different adult age groups. There are several strengths to the present study, including the low attrition rate of 13.6%, which is lower than the 25% attrition rate encountered by most weight loss studies of this duration (86). Other strengths include the use of validated questionnaires in obtaining estimated energy expenditure from physical activity, as well as in collecting exploratory information on eating behaviors through the validated IES-2 (118, 119). Additionally, the small to moderate changes in weight, body fat percent, and physical activity are probably more representative of real-world weight reduction, as opposed to studies that demonstrate significant changes over relatively short periods of time (99, 100, 102).

5. Conclusion

Although no significant differences were seen between groups in the primary outcome of RMR, we found that small changes in secondary outcomes of body fat percent and estimated physical activity energy expenditure were associated with increased fat oxidation. These data suggest that even with minor changes in physical activity and body fat, increased energy expended in physical activity may be associated with greater fat oxidation, which may favor weight loss maintenance. Additionally, learning to eat in response to physiological hunger rather than other cues was associated with improved weight loss results. Eating behavior improvements in the Eating for Physical Reasons were seen in this subsample of participants and associated with weight loss success.

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Contributors

K. Melanson and J. Beatty were responsible for design of the experiment. K. Melanson proofread the manuscript and provided valuable feedback. J. Beatty supervised the collection of data, analyzed the data, and wrote the manuscript.

Conflict of interest

There are no conflicts of interest.

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Chapter Three Tables and Figures

Table 1. Participant characteristics.

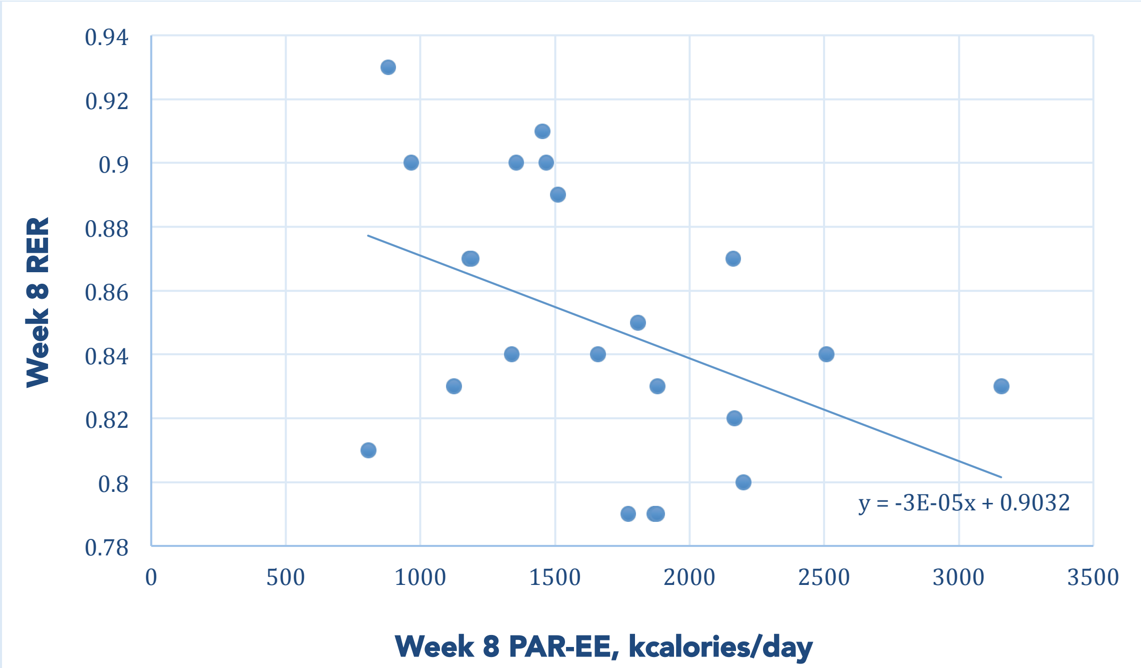
Characteristic	
	(n=22)
Mean±SD	
Age, years	34.6±16.5
Body mass index (kg/m^2)	32.0±4.3
Body fat (%)	37.5±8.6
Sex, n(%)	
Male	9(40.9)
Female	13(59.1)
Ethnicity, n(%)	
Hispanic or Latino	4(18.0)
Not Hispanic or Latino	15(68.2)
No answer	3(13.6)
Race, n(%)	
American Indian or Alaskan Native	1(4.5)
Asian	2(9.1)
Black or African American	3(13.6)
White	14(63.6)
Other	1(4.5)
No answer	1(4.5)

Table 2. Pre-post differences in predicted and measured RMR.

	Week 0	**Week 8**	***Pre-Post Difference***
Predicted RMR	1817.38 ± 263	1813.19 ± 270	0.33
Measured RMR	1817.36 ± 284	1832.05 ± 307	0.53
Metabolic Adaptation	0.02 ± 106	-18.86 ± 108	0.39

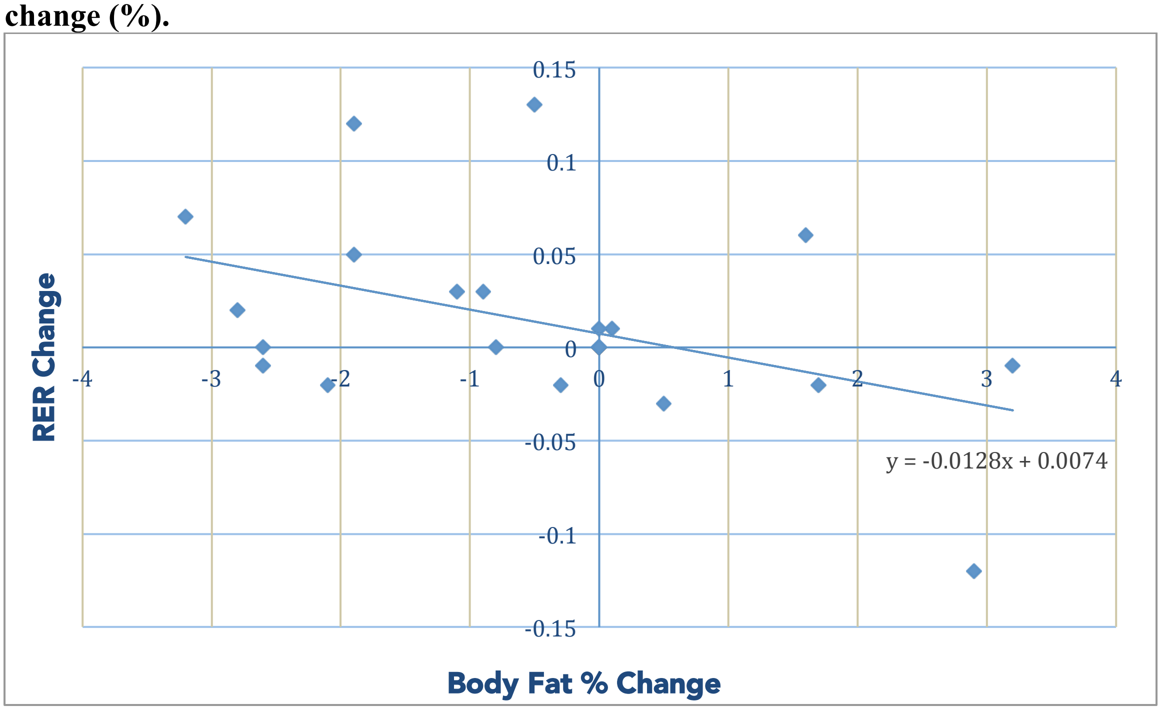
RMR = Resting metabolic rate, as measured by 45 minute measurement by indirect calorimetry, listed as kcalories/day, Mean ± SD. Predicted RMR for Week 0 and Week 8 based on multiple regression equation. Metabolic adaptation = (predicted RMR – measured RMR at Week 0) – (predicted RMR – measured RMR at Week 8). Pre-post differences calculated by paired t-tests.

Figure 1. Association between Week 8 RER (CO_2/O_2) and Week 8 PAR-EE, in kcalories/day.



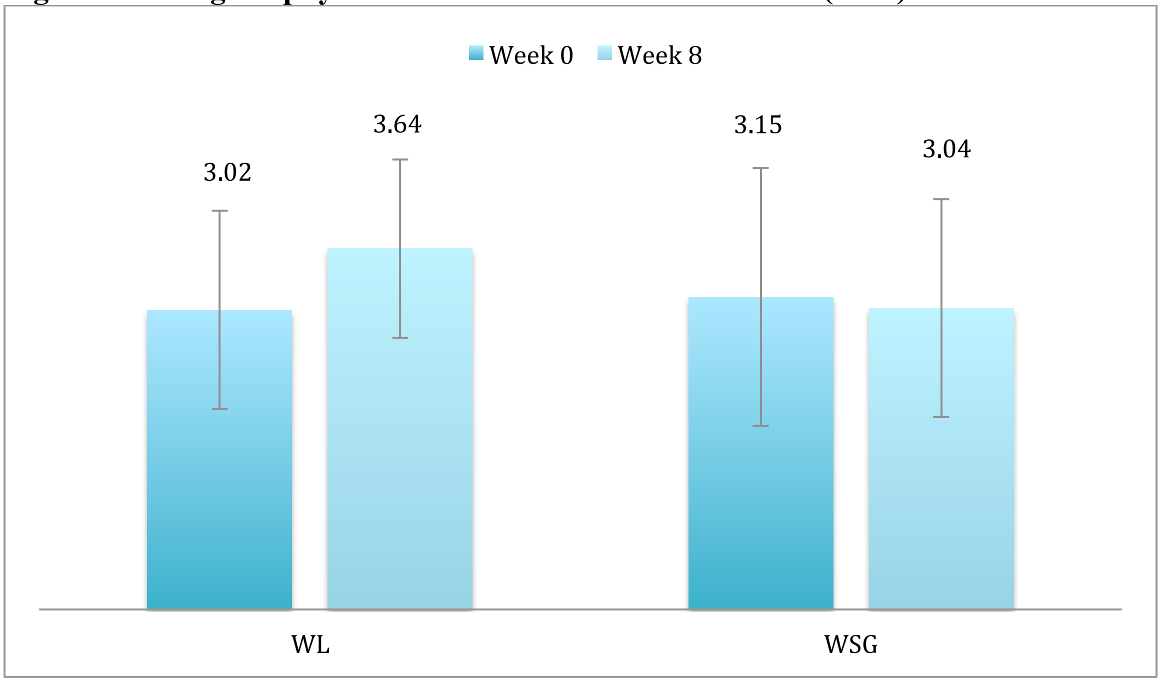
RER = respiratory exchange ratio; CO_2 = carbon dioxide production; O_2 = oxygen consumption; PAR-EE = energy expenditure as estimated by 7-day physical activity recall.

Figure 2. Association between RER change (CO_2/O_2) and body fat percent change (%).



RER = respiratory exchange ratio; CO_2 = carbon dioxide production; O_2 = oxygen consumption; RER change = Week 8 RER – Week 0 RER.

Figure 3. Eating for physical rather than emotional reasons (EPR) scores.



Results of follow-up univariate analysis to significant MANOVA, demonstrating significant time by group interaction, *p* = 0.009. WL = weight loss group (n = 13; mean age = 35.8±16.1 years; mean weight change = -2.0±1.3 kg; mean body fat percent change = -1.5±1.2%); WSG = weight stable/gain group (n = 6; mean age = 34±19.1 years; mean weight change = +1.7±1.1 kg; mean body fat percent change = +1.4±1.6%). Eating for physical rather than emotional eating scores obtained from the Intuitive Eating Scale-2, a validated tool to measure degree of adherence to intuitive eating principles (118).

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EXTENDED METHODOLOGY

Design

The completed projects are part of an ongoing program of research taking place in the Energy Balance Laboratory (EBL) at the University of Rhode Island. Project One (P1) was a within-participants experimental study, in which lab data from the Bite Counter Study (BCS) were measured to determine if there was a significant difference in eating rate when comparing eating rate in participants before and after using the first generation Bite Counter for one week. Project Two (P2) was a between groups experimental study, designed to explore the effects of the second generation Bite Counter, or ELMM, on weight loss by modifying behavior through self-monitoring, goal setting and feedback of eating rate and total bites taken as well as physical activity. Project Three (P3) was added onto P2, in which 20 participants were recruited to complete P2 as well as two additional lab visits to measure resting metabolic rate (RMR), in an effort to gather information about the metabolic adaptation that may accompany weight change. Appendix A contains a table with all hypotheses, independent variables, and dependent variables listed.

Participants and Sample Sizes

Participants were non-smokers between the ages of 18 and 48 years old (P1) and 18-60 years old (P2 and P3), have a BMI between 25 – 39 kg/m^2 and 27-40 kg/m^2 (P2 and P3), were not pregnant or lactating at the time of the study, and had no history of metabolic disease, or documented eating disorders. Participants were not taking any medications that affect appetite. Project One was a pilot study with 21 participants. Eighty participants were recruited for P2, of which 64 participants completed the study. Recruitment was based on attrition rates determined by previous studies with eating rate completed in the EBL, where ~95% of the participants were maintained during a 5 week intervention and a 6 week follow-up (47, 48). A power analysis using G*Power 3.1 (58) indicated that a sample size of 60 was needed to detect significant differences in weight loss between groups. These estimations were derived from a previous study exploring the role of technology to promote weight loss (59). A power analysis for P3 showed that recruitment of 20 participants would be required to show significant differences in RMR between groups (58, 127). This estimation was based on a previous study measuring resting and exercise energy metabolism in adults (127).

<u>Overview and Baseline Visit for All Projects</u>

Institutional Review Board (IRB) approval was obtained for all projects. Participants were recruited through advertising fliers and classroom announcements *(Appendix B).* Projects 1 and 2 required three laboratory visits (one baseline and two test visits). Project 3 also had two additional mornings of testing following each of the two original test visits from Project 2, as described later. Participants for all projects first completed a phone screening to determine eligibility to participate in the study based on the inclusion criteria. For all projects, from the baseline visit and through each subsequent lab visit, a trained researcher worked individually with each participant, one on one. Participants were asked to wear comfortable clothes with a swimsuit or fitted exercise clothing for body composition testing during baseline visit (P1) and both test visits (P2) *(Appendix C)*. During the baseline visit for all projects, informed consent was obtained. Height and weight were measured using standardized procedures to determine BMI criteria eligibility. Participants were also provided with portion size booklets during the baseline visit for all projects so that they could complete two unannounced dietary recalls by phone during the week before starting the intervention.

Procedures for Project One

During the Week 1 visit, participants were provided with a Bite Counter and instructed on its use. Participants were asked to wear the Bite Counter and were served a lab test lunch on a universal eating monitor (UEM), which measured eating rate (bites and grams per minute), bite size, pause duration, and energy intake *(Appendix D)*. Before the meal, participants completed appetite profile visual analog scales (VAS) *(Appendix E)*. After completing the meal, all participants remained in the lab for one hour without additional food or drink, and completed three additional appetite profiles (one immediately following the meal, one 20 minutes after completion of the meal, and one 60 minutes after initiation of the meal. A researcher trained in dietary recall procurement then obtained a 24-hour dietary recall from the participant. The participant was instructed to wear the Bite Counter for one week and set a goal of a 5% daily bite count reduction. Two dietary recalls were obtained by phone over the following week, and participants returned to the lab eight days later for the Week 2 lab visit, which was identical to the Week 1 lab visit. The total stipend provided for each participant was $100.00 ($20.00 each for the baseline and Week 1 visits, and $60.00 for the Week 2 visit).

Procedures for Project Two

For the Week 0 visit, participants returned to the lab after a 10-hour overnight fast, and anthropometric measurements were taken following standardized procedures, including height and weight, to calculate BMI in kg/m^2. Prior to the visit, the researcher opened the lab a minimum of 45 minutes before the scheduled visit to prepare the lab, data collection spaces and instruments for the visit. The kitchen scale was turned on to allow it to warm up for a minimum of 20 minutes prior to calibration. The Bod Pod was turned on to warm up for a minimum of 30 minutes, and after the warm up period was then calibrated and all quality controls were run as directed following standardized procedures on the morning of each participant testing. The UEM was turned on to warm up for a minimum of 20 minutes, and calibrated using the self-calibration feature of the instrument. The computer that is hooked up to the UEM was turned on, and the UEM software was opened alongside a new excel sheet by also opening Microsoft Excel. The excel sheet was saved to read: ELMM_PARTICIPANTID_WEEK0or8_DATE. Once the excel sheet was saved, the F11 key was pressed to test the recording of the UEM of both grams and time stamps every 5 seconds. If both the UEM software output and excel spreadsheet recorded a minimum of two sets of grams and time stamps, the UEM software and instrument were deemed to be functioning appropriately to run the test meal. Once deemed to be functioning correctly, the F11 button was pressed again to pause the recording until the participant would be seated and ready to consume the meal. The temperature of the room was taken and recorded by the researcher.

In the metabolic kitchen, all foods required for the oatmeal recipe were weighed according to the pre-determined weights of each ingredient, with the exception of the oatmeal itself, as the participant would choose the flavor upon coming to the visit. Once the instruments were turned on, warmed up, and calibrated, and the food was pre-weighed and ready for preparation, the researcher would set out the participant's paperwork including lab visit protocol and data collection sheet. Each sheet was pre-headed with the participant's ID number, the visit number (Week 0 vs. Week 8), and the date of the visit.

Upon coming into the lab, each participant was greeted warmly and thanked for coming to the visit and participating in the study. The researcher asked the participant if there were any questions prior to initiating the visit. Each participant was escorted to the EBL Room B where height was measured in duplicate using a digital wall-mounted stadiometer (SECA 240, Hamburg, Germany), rounding to 0.1 cm, and the average height of the two measurements was recorded. Weight was measured in duplicate using a digital scale (SECA 700, Hamburg, Germany), rounding to 0.1 kg, and the average of the two measurements was recorded. Waist circumference was measured in duplicate to 0.1 cm using a Gulick tape (North Coast Medical, Bolingbrook, IL), and the average of the two measurements was recorded. Body composition was measured by air displacement plethysmography (BodPod, Life Measurement Instruments, Concord, CA) following standardized procedures (26, 27) *(Appendix C)*. Two blood pressure measurements were taken using an automatic blood pressure monitor (Omron Healthcare, Bannockburn, IL) following standardized procedures; if measurements are greater than 5 mmHg (millimeters of mercury) apart, a third measurement will be taken, and the average of the measurements will be recorded. Fasting glucose and lipids were measured in capillary blood (Alere Cholestech LDX System, San Diego, CA) *(Appendix F)*. Body composition analysis with the Bod Pod (Life Measurement Instruments, Concord, CA), using air displacement plethysmography, was performed following standardized procedures *(Appendix C)*. Participants then had a finger-stick blood sample taken to measure fasting glucose and blood lipid levels using Cholestech (Alere, Inc., Waltham, MA) following standardized procedures *(Appendix F)*. Participants were asked while waiting for the biochemical results if he/she used a wearable device to monitor physical activity, and this information was recorded on the data collection sheet, along with the frequency of usage of the wearable device.

Participants were served a test breakfast in the lab on a universal eating monitor (UEM). Participants were then were offered a choice of oatmeal flavors: maple brown sugar (491.08 grams, 819.6 kcalories, = 1.7 kcalories per gram) or cinnamon spice flavor (=497.1 grams, 845.6 kcalories, 1.7 kcalories per gram). This mixed macronutrient standardized test breakfast consisting of oatmeal enriched with protein powder and mixed with milk and butter to approximate a 50% carbohydrate, 15% protein and 30% fat meal as analyzed by the Food Processor SQL (ESHA Research, Salem, OR). Participants were also offered a choice of spring water, hot decaffeinated coffee or hot decaffeinated tea with no additives. Laboratory lunch conditions were standardized, as all participants fasted before the meal and were advised to abstain caffeine as part of the fasting, and to avoid exercise the morning of the laboratory visit. The exact time of start and stop of the test meal were covertly recorded, and the Universal Eating Monitor recorded grams of the meal every five seconds and transferred these data to an excel file. The beginning and end weights of the meal were taken using a kitchen digital scale and recorded, and the amounts of oatmeal and water or hot beverage consumed were recorded using weighted differences. The calculation of eating rate of the test meal was done using both grams and kcalories consumed, divided by the number of minutes of the meal duration.

Immediately before the meal and directly after the participant finished eating, the participants completed VAS appetite scales. After the completion of the meal completion VAS scale, participants were asked to give an in-person 24-hour dietary recall using a multiple pass method by the trained researcher, who would also administer a 7-Day Physical Activity Recall. To complete this recall, the researcher asked the participant about the type, intensity, frequency and duration of physical activity that they have participated in during the previous seven days using the validated 7-Day PAR (105, 106). Participants are then asked to complete the Weight-Related Eating Questionnaire (128) *(Appendix G)* on their own. The participants in the control group were introduced to the weight loss intervention, which is a workbook that provides information to guide the participants through eight weeks of lessons on how to reduce eating rate (*Appendix H*). These concepts have been tested in the Energy Balance Lab as previously discussed. The intervention workbook also covers how to reduce energy density of food and beverages consumed. Participants in the experimental group were given the same instructional workbook in addition to instructions about how to use the ELMM, as well as goal sheets for bite count and step count *(Appendix I)*. The information included how to wear the ELMM as well as how to download data electronically from the device for self-monitoring and goal setting. For both groups, the researcher reviewed the workbook with them, identifying the three main metrics of the study: bites, steps, and eating rate. The researcher specified that the participants did not have to bring the workbook back to the lab for subsequent visit(s), and that no one would be checking up on their use of it; however, participants were encouraged to use the workbook and to try to complete each week's suggested "homework' tasks. Lastly, all of the participants were asked to perform a standardized three-minute step submaximal step fitness test *(Appendix J)*.

The intervention between Week 0 and Week 8 lasts eight weeks, during which the participants followed the weight loss intervention as outlined by their workbooks. Both the control and experimental groups received periodic standardized emails from the research team *(Appendix K)* reminding them to use their workbook. Additionally, the experimental group received a reminder to download their weekly data from the ELMM and to send their data to the research team. If participants did not send their data to the research team, the team followed a protocol for contacting them *(Appendix L)*. Upon receiving weekly data from each participant, the research team provided individualized feedback to participants via email. The last lab visit (week 8) was the same as the Week 0 visit as described previously, with the exception of introducing the intervention and workbook. The total stipend provided to each participant was $160.00; $20.00 was awarded at the baseline visit, $40.00 was awarded at the Week 0 visit, and $100.00 was provided to each participant who completed the eight week study and Week 8 visit.

Procedures for Project Three

Twenty participants were recruited to participate in P2 and were asked to participate in the add-on study (P3), which would examine metabolic rate in response to the weight loss intervention. Each participant was provided with an additional stipend of $20.00 for each of the two additional visits) to complete two supplementary lab visits at both Weeks 0 and 8. Before these visits, the researcher opened the lab at least 30 minutes before the start time of the visit to allow adequate time for calibration of the Indirect Calorimeter (IC) (Vmax Encore 29, Care Fusion, Palm Springs, CA). The IC was left on overnight before the visits to ensure that the instrument was adequately warm for calibration. The researcher unscrewed the tops of both oxygen/carbon dioxide tanks by turning the tank wrench four times to the right, and then twisted the pressure caps four times to counterclockwise. The researcher then performed all flow calibration quality control steps as directed according to standard procedures, and subsequently entered the participant's information into the IC.

Participants came into the lab after a 10-hour fast the one to two days after the previously described Week 0 and 8 visits. Upon entering the lab, the researcher confirmed fasting state and asked participant to remove shoes and any excess bulky clothing other than light street clothing. Participants were then led into the adjoining climate-controlled metabolic testing lab for indirect calorimetry testing *(Appendix N).* Participants were first weighed to record the weight of that day, to account for any changes since the previous day or overnight. Participants were asked to lie in a supine, elevated position on the laboratory bed for a 30-minute pre-test resting period, and the researcher explained that the initial 30 minutes would be the resting period, during which time participants were asked to complete three questionnaires: the first is the Intuitive Easting Scale (IES-2) (107, 108) *(Appendix M)*, to assess baseline and post-intervention feelings towards eating, with a focus on internal cues for eating. The second questionnaire was the Sleep Questionnaire, and the third was the Cohen Perceived Stress Survey; the data and potential findings from these surveys will be published elsewhere. Flow rate and gas calibrations were performed using two calibration tanks containing different CO_2 and O_2 concentrations, as directed by the manufacturer's instructions. Participants then underwent a 45-minute measurement of RMR and respiratory exchange ratio (RER; VCO_2/VO_2) by ventilated hood indirect calorimetry. Participants were asked to refrain from sleeping, writing, or using their phones in any way. Participants were monitored closely to assure compliance with the protocol. A ventilated hood was placed over the upper body of the participants lying in a supine position, and measurements of RMR and RQ were taken by the indirect calorimeter for a period of 45 minutes. Throughout this time period, acquired VO_2 and CO_2 were converted into RMR by the indirect calorimeter using the Weir equation. Upon completion of measurements, participants received a printed copy of their resting metabolic measurements, and were offered a choice of two different flavored breakfast bars and choice of juice box or water before leaving the lab.

Instruments

The following section details the instruments that were used in this study:

Anthropometric (P1 and P2) and Biochemical (P2) Data Collection

Height was measured in duplicate using a digital wall-mounted stadiometer (SECA 240, Hamburg, Germany), rounding to 0.1 cm, and the average height of the two measurements was recorded. Weight was measured in duplicate using a digital scale (SECA 700, Hamburg, Germany), rounding to 0.1 kg, and the average of the two measurements was recorded. Waist circumference was measured in duplicate to 0.1 cm using a Gulick tape (North Coast Medical, Bolingbrook, IL), and the average of the two measurements was recorded. Body composition was measured by air displacement plethysmography (BodPod, Life Measurement Instruments, Concord, CA) following standardized procedures (26, 27) *(Appendix C).* Two blood pressure measurements were taken using an automatic blood pressure monitor (Omron Healthcare, Bannockburn, IL) following standardized procedures; if measurements are greater than 5 mmHg (millimeters of mercury) apart, a third measurement will be taken, and the average of the measurements will be recorded. Fasting glucose and lipids were measured in capillary blood (Alere Cholestech LDX System, San Diego, CA) *(Appendix F).*

EATING RATE MEASUREMENT: *Universal Eating Monitor (P1 and P2)*

The Universal Eating Monitor (Mettler Toledo, Columbus, OH) is a self-calibrating scale that has been validated for its accuracy in measuring grams of food consumed by participants during a meal in the laboratory setting (54). The initial weight of the meal, minus the weight of the bowl, was recorded, and at the end of the meal, the final weight of the meal, minus the bowl, was recorded. Recording the number of minutes and seconds that the participant eats allowed assessment of the duration of the meal. To obtain eating rate, the number of grams of food consumed were divided by the duration of the meal in minutes and seconds, and this provides an eating rate in grams consumed per minute *(Appendix D).*

HUNGER, SATIETY AND APPETITE MEASUREMENTS: *Visual Analog Scale (P1 and P2)*

The VAS has been validated for use in assessing participant hunger and appetite in test meal studies (129). The VAS was administered to the participants (P1 and P2) four times per lab visit: immediately before consumption of in-lab test meals, upon completion of the meals, 20 minutes after meal completion, and 60 minutes after meal initiation. These scales are tools that ask participants to rate their hunger, satiety and desire to eat on a line, which was later measured by the researchers and marked as falling between 0 and 10 mm *(Appendix E).*

ENERGY INTAKE MEASUREMENTS: *24-Hour Dietary Recall (P1 and P2)*

Multiple-pass, 24-hour dietary recalls were administered by a member of the research team who has been trained in administering dietary recalls to participants. The researcher recorded specific brand names, amounts, and serving sizes. Dietary recalls have been analyzed using Food Processor SQL software (ESHA, Salem, OR) to obtain energy intake measurements.

PHYSICAL ACTIVITY MEASUREMENTS:

7-Day Physical Activity Recall (PAR) (P2)

Participants were interviewed about the type, intensity, frequency and duration of physical activity that they have participated in during the previous seven days using the validated 7-Day PAR (105, 106). This allows researchers to compare information about the level of physical activity participants are participating in before and after the intervention.

Queens College Step Test (P2)

The Queens College Step Test is a submaximal test to assess the aerobic capacity of the participants *(Appendix x).* In this test, the researcher measures resting pulse rate before and after three minutes of stepping onto the step in order to predict the participant's maximal volume of oxygen consumption (VO_2 max) using a regression equation based on the participant's gender and pulse rates. This validated test (130, 131) does not push the participants to maximal capacity, which may be contraindicated in this population. Instead, the simple step test and accompanying calculations will provide estimates of maximal aerobic capacity. The test involves a 16.25-inch step, a metronome, and a stopwatch. The step-by-step protocol is outlined in *Appendix J.*

BEHAVIORAL MEASUREMENTS: *Questionnaires (P3)*

The *Weight Related Eating Questionnaire (WREQ) (Appendix G)* is a 16-item, four-factor questionnaire. The WREQ is a validated questionnaire designed to measure theory-based aspects of eating habits of participants (53), which will provide information about the eating habits of the participants for comparison of before and after the intervention. All domains of the WREQ were examined, with a focus on 'external eating' and 'emotional eating'. The *Intuitive Eating Scale* (IES-2) *(Appendix H)* was used to assess baseline and post intervention feelings towards eating, with a focus on internal cues for eating. The IES-2 is a validated four-subscale tool measuring degree of adherence to intuitive eating principles (107, 108).

METABOLIC MEASUREMENTS: *Indirect Calorimeter (P3)*

The indirect calorimeter (Vmax, Sensormedics, Yorba, CA) is an instrument that measures RMR and RER by way of respiratory gas collection under the hood of the instrument while participants lie in an elevated supine position, according to manufacturer's instructions *(Appendix N)*.

Statistical Analyses

Throughout data collection from July 2016 – October 2017, data entry was continuous and recorded on an Excel master spreadsheet. Multiple tabs were created to correspond with the participants' groups and specific data collected each visit. For example, a tab was created in which lab assistants recorded all basic demographic information for the experimental group participants, including age, race, and ethnicity.

Another tab was created to record the same information for the control group. Tabs were created to record anthropometric data for each group, as well as biochemical data, 7-day physical activity recall data, scores for the visual analog scales, scores for the Weight Related Eating Questionnaire, and the Intuitive Eating Scale.

All data were analyzed using SPSS, version 24 (Statistical Package for Social Sciences, IBM-SPSS Inc.). All data were examined for normality, skewness and kurtosis. If non-normal data were found, data were normalized or nonparametric tests were used. Any violations to assumptions were addressed and corrections were incorporated into analyses as needed. The presence of potential outliers was identified using Q-Q plots and boxplots, as well as stem-and-leaf diagrams, which identify extreme values. In an effort to keep as many data points as possible, the attempt was made to keep outliers if justification was found to describe their influence. Data were presented as means ± standard error of the mean (SEM), unless otherwise noted. Repeated measures ANOVAs were used in P1 to compare eating rate before and after participants wear the Bite Counter for one week. No significant differences were found, and this information was explored further to identify normative value parameters to apply to raw free-living bite count data (see abstract and poster in Appendix X).

For Chapter One/Manuscript One, the following statistical tests were used:

Descriptive statistics were used to summarize demographics using means, standard deviations, and frequencies to examine skewness and kurtosis. Independent *t* tests were used to identify between group differences in continuous variables and chi square tests of homogeneity were used to identify between group differences in nominal variables at baseline. Repeated measures analyses of variance (ANOVA) were run to determine group differences in primary and secondary outcomes. Outliers were identified using Q-Q and box plots. At week 8, participants were grouped into weight loss and weight stable/gain groups, Wilcoxon Mann-Whitney tests examined differences between groups in week 0 scores and in week 8 scores. Repeated measures ANOVA examined between group differences in WREQ score changes from week 0 to week 8. Spearman's correlations examined associations between week 0 WREQ scores and body weight change from week 0 to week 8, and Pearson's partial correlations examined differences between WREQ score change and body weight change in all participants. All statistical tests were two-tailed, and considered significant at the 0.05 level.

For Chapter/Manuscript Two, the following statistical tests were used:

Descriptive statistics were used to summarize demographics using means, standard deviations, and frequencies to examine skewness and kurtosis. The primary outcome of this study, eating rate as measured by the ELMM device, was examined using one-way analysis of variance (ANOVA) to determine group differences between eating rate categories. The five eating rate categories were collapsed into three categories due to the low number of participants who self-reported their eating in the extreme categories ("very slow", n = 1, and "very fast", n = 6). Therefore the "very slow" and "slow" categories were combined into one "slow" category, and the "fast" and "very fast" categories were combined into one "fast" category. Q-Q and box plots were used to identify potential outliers. Spearman's correlations examined associations between SRER scale and BCI as recorded by the ELMM device. All statistical tests were two-tailed, and considered significant at the 0.05 level. Effect sizes were calculated using Cohen's d for *t* tests and partial eta squared (η^2) for ANOVAs and repeated measures ANOVAs. All data were analyzed using SPSS, version 24 (Statistical Package for Social Sciences, IBM-SPSS Inc.).

For Chapter/Manuscript Three, the following statistical tests were used:

Descriptive statistics were used to summarize demographics using means, standard deviations, and frequencies, and to examine skewness and kurtosis. Independent t tests were used to examine differences between groups at the beginning of the intervention. Repeated measures ANOVAs were used to examine between group differences in primary outcomes, RMR and energy expenditure. Outliers were identified using and boxplots and stem-and-leaf diagrams. Paired t-tests examined changes over time, and correlations explored associations among body fat percent, PAR-EE and RQ in all participants.

In order to create a linear regression model to predict RMR in this subject pool, baseline data were used to determine if a regression model would be a good fit for the data. A least-squares best-fit model was generated to determine RMR based on age, sex, lean body mass (LBM), and fat mass (FM). The model showed that these four independent variables were a statistically significantly better fit to the data than the mean model ($F_{4,95} = 26.43$, $p<0.001$).

$$\text{RMR (kcalories/day)} =$$

$$738.33 - (166.023 \times \text{sex}) - (0.738 \times \text{age}) + (15.872 \times \text{LBM}) + (8.236 \times \text{FM})$$

R^2 for the overall model was 0.86, with an adjusted R^2 of 0.83, demonstrating that 83% of the proportion of variance in predicted RMR could be explained by age, sex, LBM and FM. Therefore this prediction equation was used to estimate predicted RMR based on age, sex, lean body mass and fat mass.

Metabolic adaptation was defined as the difference between predicted RMR as calculated based on the least squares linear regression equation, and measured RMR by indirect calorimetry:

Metabolic Adaptation = Post intervention predicted RMR – Measured RMR

All significance testing was two-tailed, and significance was accepted at $p < .05$. Effect sizes were calculated using Cohen's d for *t* tests and partial eta squared (η^2) for ANOVAs and repeated measures ANOVAs. All data were analyzed using SPSS, version 24 (Statistical Package for Social Sciences, IBM-SPSS Inc.).

Time Line for Project One

April-August 2015: IRB Approval, Material Preparation, Training, Participant Recruitment
September 2015-May 2016: Participant Testing 2-3 Participants per month; Data Entry
May-June 2016: Data Entry and Double-Checking
July 2016-January 2017: Data Assimilation and Analyses; Preparation of Tables and Figures; Data Interpretation
February-May 2017: Finalize Manuscripts

Time Line for Project Two

April-July 2016: IRB Approval, Material Preparation, Training, Participant Recruitment
July 2016-May 2017: Participant Testing 6-10 Participants per month
September 2016-April 2017: Data Entry and Double-Checking
March-June 2017: Data Assimilation and Analyses
July-October 2017: Preparation of Tables and Figures; Data Interpretation
November 2017-February 2018: Finalize Manuscripts

Time Line for Project Three

December 2016-January 2017: IRB Approval, Material Preparation, Training, Participant Recruitment
February-May 2017: Participant Testing 5-8 Participants per month
March-June 2017: Data Entry and Double-Checking
June-September 2017: Data Assimilation and Analyses
October-December 2017: Preparation of Tables and Figures; Data Interpretation
January-February 2018: Finalize Manuscripts

Resources Required and Utilized

Funding for supplies and participant stipends was obtained through a grant awarded by the Obesity Society. All data collection took place in Fogarty Hall, at the University of Rhode Island, Kingston, RI in the Energy Balance Laboratory (EBL) and in the Common Intake Area (CIA). Departmental equipment including the Bod Pod, scale and stadiometer, Cholestech analyzers, indirect calorimeter and Queen's College Test materials were used. Lab computers in the EBL currently contain all the software needed for data management and analysis including SPSS, the Statistical

Package for Social Sciences, as well as Elizabeth Stewart Hands and Associates' (ESHA) Food Processor SQL 9.0 (ESHA Research, Salem, OR) Food Processor Nutrient Analysis Software. The Bite Counters have been donated by and the ELMM devices have been purchased from Bite Technologies, Inc. (Clemson, SC), using funding from the Obesity Society Grant. No other university resources were required for these studies, with the exception of the use of another Bod Pod, located within the Department of Kinesiology, Independence Square, Kingston, RI, for one participant only upon technical difficulty with the Nutrition Department's Bod Pod. This Bod Pod was also warmed up appropriately and the same trained researcher who ran the other participants' visits also calibrated the Bod Pod and ran all quality controls before the use of this instrument with a participant.

EXTENDED LITERATURE REVIEW

Introduction

Obesity continues to be prevalent nationally and globally, and contributes to the many health-related and financial burdens faced by our country and throughout the world. The causes of obesity are many, and encompass behavioral mechanisms including eating rate. Eating rate has been shown to affect obesity-related conditions including high body mass index, glucose intolerance, and undesirable adipose distribution. Weight reduction, even in small amounts, has been shown to reduce the health burden of those at risk for developing obesity-related disease. Self-monitoring is considered to be a critical component to weight loss success; however, a way in which eating rate can be self-monitored in free-living settings is currently lacking in the prevention and treatment of obesity. The Bite Counter is a newly develop wearable device that is worn like a watch and has been designed to detect bites, steps and eating rate. This device has been untested in its application of monitoring free-living eating rate, and has the potential to assist in weight management by this self-monitoring application. Further, the potential effects of weight loss through the use of this device on metabolic adaptation, or the reduction of RMR that is not attributable to changes in body weight or in body composition, has not been tested to date.

Therefore, the aim of this literature review is to explore the research on four main human adult nutrition-based areas of study: 1) eating rate and its association with obesity, metabolic risk factors, and energy intake, and its potential role in weight loss; 2) the role of self-monitoring and goal setting as it relates to weight reduction; 3) a new wearable device, capable of tracking bites, steps, and eating rate; and 4) the effects of weight reduction on metabolic adaptation. The scope of this review entails the previously published eating rate literature in adult human nutrition, as it has been studied along with its associations with body mass index (BMI) and energy intake. Secondly, the importance of self-monitoring and goal setting as it pertains to weight loss-related behavioral feedback will be discussed. Next, all research pertaining to a novel wearable device capable of providing real time feedback to the user will be examined, including its validity and recent applications, as well as its potential in self-monitoring as an aid in weight management. Finally, the effects of weight reduction on metabolic adaptation will be reviewed, as well as the effects of decreased body mass, decreased body fat, and increased lean mass on RMR. The participant of obesity, the well-documented benefits of weight loss, and the importance of uncovering new ways to promote sustainable habits that lead to healthy weight management are vital, because millions of people in our country and around the world are diagnosed with comorbidities that are caused by or related to obesity.

Obesity

Prevalence and Causes of Obesity in the United States

Overweight and obesity continue to rise globally (132). In 2013, the proportion of adults with a Body Mass Index (BMI) of 25 or greater increased from 28.8% in 1980 to 36.9% for men, and increased from 29.8% to 38.0% for women (132). Obesity has increased in the United States 0.6% each year between 2005 and 2012. Obesity has long been established as an independent risk factor for diabetes, cardiovascular disease, stroke, cancer, and overall mortality (133-135). Moreover, the financial estimated costs of obesity-related medical care further highlight the healthcare burden of obesity: the estimated medical costs of obesity have grown in the United States from $147 billion in the year 2008, to $190 billion in 2012 (136, 137). A recent systematic review of the absolute and relative costs of obesity worldwide demonstrated that medical expenditures associated with obesity range from 0.7% to 2.8% of a country's total healthcare costs, and when costs associated with overweight were added, the percentage of healthcare costs increased to over 9% (138, 139). Additionally, it is estimated that individuals with obesity that is classified as a BMI > 30 kg/m^2 have medical costs approximately 30% higher when compared to individuals with a BMI < 25 kg/m^2 (139).

Effects of Weight Loss on Comorbidities in the United States

Research has demonstrated the favorable effects of weight loss on comorbidities in those who fall into the overweight and obese categories (135, 140). Even a small weight loss of 5-10% in those with obesity with associated comorbidities has been shown to improve outcomes such as the prevention of type 2 diabetes (T2D), decrease hyperglycemia, improve blood lipid panels, reduce hypertension, and decrease in incidence of gastric esophageal reflex disease (135, 140). Anderson and Konz (37) reviewed the literature on body weight, weight gain, and weight loss on coronary heart disease (CHD), and found a significantly higher risk for CHD in young people with a higher body mass index (BMI) when compared to those with a lower BMI. For every percentage point above a healthy BMI, the risk for CHD increased by 3.6% for men and 3.3% for women (37). It was also determined that for every kilogram of weight gain after high school, the risk of developing CHD increased by 3.1% for men and 5.7% for women

(37). Conversely, this research also showed that weight loss significantly decreased a series of CHD risk factors: for every one kilogram of weight loss, there was an associated change in fasting serum cholesterol of -1.0%; low-density lipoprotein of -0.7%; triglycerides of -1.9%; high-density lipoprotein cholesterol of +0.2%; -0.5% in systolic blood pressure and -0.4% in diastolic blood pressure; and a change in blood glucose of -0.2mM (37).

Studies have also examined the effects of weight loss on cognition, risk of diabetes, and all-cause mortality. A recent systematic review and meta-analysis of 20 studies, focusing on 13 longitudinal studies and 7 randomized controlled trials, found significant positive associations between weight loss and improvements in cognitive function, including attention and memory (141). In the Diabetes Prevention Program, participants were randomized into an intensive lifestyle intervention to promote weight loss, which included changes in diet and physical activity; results showed that for every kilogram of weight lost, the risk of diabetes was reduced by 16% (142). Additionally, in that study, even those participants who did not meet the weight loss goal but who had met the goal for increased physical activity, demonstrated a 44% lower incidence of diabetes (142). Kritchevsky and colleagues conducted a meta-analysis of studies and found that an average 5.5 kg weight reduction led to a significant 15% reduction in all-cause mortality (143). A longitudinal study by Li and colleagues demonstrated that weight reduction led to up to a 41% reduction in cardiovascular mortality after 23 years of follow-up (144). The findings from these studies highlight not only the clinical significance of weight loss, but places increased value on incorporating physical activity into lifestyle interventions, and demonstrate that even a small weight loss can have clinically significant implications on the health and well-being of obese persons. Therefore, research efforts should be focused on ways to help promote weight loss in an effort to reduce the prevalence of comorbidities associated with obesity.

As critical as the achievement of weight loss to reduce obesity and its associated comorbidities is, consideration must be given to the importance of weight maintenance to achieve the positive health improvements attributed to weight reduction. One key concept that has been associated with the ability to maintain weight loss is adaptive thermogenesis, otherwise known as metabolic adaptation. Metabolic adaptation is defined as a reduction in RMR (RMR) as a result of weight loss, which is greater than would be expected based on the amount of weight lost (87, 88). This phenomenon has been well documented in the literature; in the presence of a negative energy balance, RMR decreases further than would be expected from reductions in body mass and changes in body composition (87-89). Furthermore, the existence of this state likely contributes to the difficulty of obese individuals to lose and maintain a healthier weight (87, 90).

Causes of Obesity and Eating Rate as a Potential Modifiable Factor

The factors contributing to obesity are many, and range from genetic and environmental factors to a multitude of behavioral factors. Behavioral factors include increases in food consumption and changes in diet composition, as well as declining levels of physical activity (145, 146). In 2014, only 21% of adults in the US met the recommended levels of physical activity (147). Four of the top ten leading causes of death in the United States may be reduced with improved nutrition and physical activity (147). Effective intervention for behavior change that supports reduced energy intake and increased physical activity levels are critically important to the future health and well-being of those who fall into the high-risk categories of obesity.

One behavior that has been associated with obesity is eating rate, or the amount of food consumed per unit of time (3-6). Longitudinal studies have demonstrated a relationship between eating rate and obesity; in a study exploring predictors of weight increase in a sample 438 fire service workers over a 7 year period, personnel who reported a habitual faster eating rate at time point one experienced a significantly increased weight 7 years later (5). A systematic review and meta-analysis of 23 studies, mostly cross-sectional, revealed a positive association between eating rate and obesity (3). Population studies have demonstrated a positive association between eating rate and weight gain over time; in a sample of 529 male Japanese workers, those who self-reported as fast eaters had significantly higher weight and BMI at two different time points 8 years apart; furthermore, when compared to slow eaters, the fast eaters gained significantly more weight between the two time points (6). In addition to its establishment as a potential underlying contributor of obesity (3, 7), rapid eating rates have also been positively associated with excess body fat and central fat distribution (8, 9), and insulin resistance (10).

Faster eating rates have also been shown to be positively associated with energy intake in experimental studies. In a randomized crossover design examining eating rate and energy intake in both normal weight and obese participants, those in a fast eating condition had a higher energy intake compared to those in a slow eating condition (11). Moreover, decreasing eating rate has been associated with reductions in energy intake in 30 healthy young women (12). A systematic review and meta-analysis demonstrated that slower eating rates lead to significantly reduced food intake, and that the measure for eating rate reduction did not matter, as all led to reduced intake (13). Results from this meta-analysis also showed that greater reductions in eating rate were associated with greater reductions in energy intake. This information provides a solid foundation for further consideration of eating rate as a potential key behavior in obesity management.

Eating Rate

Eating Rate, BMI and Energy Intake

Eating rate has been shown to affect a variety of mechanisms related to weight status and obesity, especially in the context of overweight and obesity. For example, higher eating rates have been demonstrated in severely obese men and women with increased central fat distribution (8). The speed at which people consume food has also been shown to be positively associated with body mass index (BMI), as well as with energy intake (EI). Rapid eating rates have been established as a potential underlying contributor of high BMI and excess body fat (4, 148-150). Small within-laboratory studies conducted in the Energy Balance Lab at the University of Rhode Island have shown that higher eating rates are associated with increased energy intake; additionally, the findings of these studies have shown that eating rate is a behavior that can be changed with education and as a result can decrease energy intake (47, 48). Such findings are promising to obesity-related research, because they present a behavior that is changeable and that may potentially affect energy intake, which is a critically important component of obesity prevention and treatment. However, the relationship between reducing eating rate and weight loss has not yet been explored.

A review of the literature on eating rate demonstrates the much has been done in the way of exploring the association between rate of eating and the presence of obesity. Research has also investigated associations of eating rate and body fat, as well as associations between eating rate and insulin resistance. These explorations have been conducted through a number of different study designs, including a systematic review and meta-analysis, epidemiological and longitudinal studies, and numerous cross-sectional studies. This review will first explore the publications relating to eating rate and BMI/obesity, followed by the research exploring associations between eating rate and energy intake, and finally explore studies that have begun to examine the effects of reducing eating rate on energy intake. This review will also demonstrate that a significant research gap exists in the eating rate literature to date: free-living eating rate has not been tested within a weight loss intervention, nor has it been validated against self-reported or laboratory-measured eating rate.

Eating Rate and BMI in Cross-sectional Studies

The next section will review the literature on eating rate and BMI in cross-sectional studies. In an older cross-sectional study published in 2003 by Sasaki et al., a sample of 1,695 18-year old Japanese dietetic students was conducted to examine potential associations between eating rate and BMI, as well as between eating rate and macronutrient distribution and dietary fiber intake (7). Two questionnaires were administered, one of which was the Diet History Questionnaire (DHQ), a validated dietary recall questionnaire that collects information including self-reported height and weight, and another questionnaire which included speed of eating as categorized by five qualitative categories: very slow, relatively slow, medium, relatively fast, and very fast. Results of that study demonstrated that with rates of eating as independent variables, there was a significant increase in BMI with each increase in eating rate category (7).

Limitations of that study include the self-reporting nature of height and weight, as well as the previously mentioned self-reported eating rate through self-administered questionnaire. However, in preliminary work, these researchers examined the validity of these eating rate categorical questions by asking a subset of these participants to answer them, and then asking a close friend what that person's usual rate of eating is (7). The results of this portion of the research demonstrated good agreement between self-reported and friend-reported eating rates. Therefore this paper lends two useful implications to the eating rate research, even in its early phases from the early 2000s. First, it identifies correlations between self-reported eating rates and friend-reported eating rates, a finding that is referred to frequently throughout the eating rate literature; and second, it was one of the first studies to identify a significant positive association between eating rate and BMI.

In a study published in 2008 by Maruyama and colleagues in Japan, associations between eating until full and eating quickly with overweight were explored in a sample of 3,287 adults (1,122 men, 2,165 women) from two communities in Japan (36). The instrument used was a validated self-administered brief questionnaire on diet history, which asked whether they usually eat until full (yes/no question) and about their usual speed of eating. Speed of eating was divided into five categories: very slow, slow, medium, fast, or very fast. Due to the low number of participants who self-rated in the very fast category, the very fast and fast categories were combined into an eating quickly category. Categories of medium, slow and very slow were also combined to make a slower eating category. The authors mentioned the previously cited publication by Sasaki et al. with agreement of friend-reported ER using same questionnaire. The multivariate adjusted odds ratios for overweight, after adjusting for age, total energy intake, fiber and alcohol intakes, smoking status, physical activity and area in which the survey was completed was 1.84 (95% CI: 1.42-2.38) for men and 2.09 (95% CI: 1.69-2.59) for women. The eating until full group also had significantly higher adjusted odds ratios; and when combined together to explore if there was an additive effect of eating until full on top of eating quickly, there were significantly higher adjusted odds ratios of 3.13 (95% CI: 2.20-4.45) for men and 3.21 (95% CI: 2.41-4.29) for women. There were significant positive associations between eating quickly and eating until full and overweight in Japanese adult men and women, and this held even after adjusting for age, energy intake, and other potentially confounding variables.

Strengths of the study include that the researchers used standardized methods to have participants complete surveys to minimize researcher bias; height and weight were objectively measured; data on smoking status, physical activity and occupation were collected; population-based data were used. Limitations of the study included that SRER was used; also no validation exists of the eating until full question. Additionally, other potential confounding factors such as education level or income level were not accounted for, and the cross-sectional study removes causality between the identified associations. However, the results demonstrate that eating fast continues to show associations with overweight, even after controlling for many confounders, including energy intake, further supporting the eating rate and overweight literature.

Kimura and colleagues in 2011 set out to examine if eating behaviors were associated with overweight in a sample of adult Japanese working men (151). They recruited 290 men who worked in two municipal offices in northeastern Kyusyu, Japan, asked participants to complete a self-administered survey that addressed lifestyle behaviors, with yes/no questions relating to five eating behaviors, one of which was eating rate ("Do you tend to eat quickly?"). Logistic regression was used to examine associations between eating behaviors and overweight. An eating behavior score was created based on the number of "yes" answers to 5 eating behavior questions. Results showed that the odds of being overweight increased as the overall eating behavior score increased. Additionally, the multivariate adjusted odds ratios for overweight for eating quickly (4.33 [95% CI: 2.46, 7.64]) showed a positive association between eating quickly and overweight in middle-aged Japanese men.

That study had both strengths and limitations; strengths of the study included that the researchers controlled for possible confounding factors, such as diet and lifestyle factors such as physical activity, smoking status and job stress. Limitations of that study include that the researchers collected data from 198 women in addition to the 290 men, but excluded the women's data; the reason provided in the paper was that there has been an increase in overweight in men in Japan, so they decided to focus this research on the men only (151). These researchers also used a dichotomous question to collect eating rate information, which may be restrictive in terms of information that might be gained from a 5-point scale as in previous studies (7, 36). Other limitations include lack of causality due to the nature of cross-sectional study; small sample size to detect moderate associations; the dietary questionnaire was not previously validated; and there was a lack of generalizability to other populations. However, that study contributes to the published literature that speaks to the positive association between eating rapidly and body mass.

One limitation of the research done in the eating rate area to date is that many of the studies have been done in the Asian population, and primarily in Japanese participants. This may limit their generalizability to other populations. However, Leong and colleagues examined associations between self-reported eating rate (SRER) and BMI in a New Zealand population study (152). In this cross-sectional study, a sample of 2500 women between the ages of 40 and 50 years completed self-rated eating rate questions via a self-administered questionnaire, and a significantly higher BMI of 2.8% was identified for each increase in self-reported speed of eating (categorized as 'very slow', 'relatively slow', 'medium', 'relatively fast', 'very fast') (152). Linear regression models were used to look at the univariate associations between demographic, health and behavioral variables and BMI. A multivariate regression model was used to examine associations between SRER and BMI while adjusting for age, smoking status, menopause status, thyroid condition, prioritized ethnicity, socioeconomic status, and physical activity. A positive association was found between SRER and BMI both before adjusting (3.1%, 95% CI: 1.8-4.5%, p <.001) and after adjusting for all variables (age, smoking status, menopause status, thyroid condition, prioritized ethnicity, socioeconomic status, and physical activity (2.8%, 95% CI:1.5 to 4.1%, p <.001). Therefore BMI increased by 2.8% for every one-category increase in SRER, even after adjusting for demographic, health, and behavioral variables listed above. Although the cross-sectional design of that study makes it difficult to establish causal relationships, it is important to recognize that that study has demonstrated an association between eating rate and BMI in a non-Asian population. These findings are of particular clinical significance because the reduction in BMI with each SRER category is equivalent to the same recommended reduction in weight recommended to diminish the risk of developing diabetes and cardiovascular disease in obese men and women (142).

Leong and colleagues also published a prospective study examining eating rate and changes in BMI after three years in the sample of New Zealand women previously reviewed. The originally study published in 2011 identified higher BMI with faster categories of eating rate (152); the more recent study published in 2015 used the same nationwide population survey data to compare baseline BMI and eating rate with the same parameters three years later (153). A sample of 1,015 New Zealand women 40-50 years old were randomly selected from nationwide electoral rolls, and were asked to complete the same self-administered questionnaire described in 2011 Leong study (152). The participants were classified into new categories of eating rate because there were few slow eaters; very slow and relatively slow and medium eaters were combined to make a new "slower eaters" category; and relatively fast and very fast eaters were combined to make a "faster eaters" which had been done in previous studies (6, 36).

Results from that study showed that regarding baseline and three-year self-reported rates of eating, participants who classified themselves as faster eaters had significantly higher weight, BMI and BMI category (all $p<0.001$). There were no statistical differences between baseline speed of eating and 3 year follow up speed of eating, and no significant differences between BMI change over 3 years and BMI category change (all $p>0.1$). This also suggests that eating rate is a relatively stable trait in the absence of eating rate change intervention. The longitudinal design was a strength of that study; also had a nationally represented sample; good response rate at baseline (66%) and 3-year retention rate (79%) (153). However, these researchers continue to rely on the self-reported eating rate question, as well as in this case, self-reported height and weight measurements, which may be subject to underreporting. However, that study sheds further light on the eating rate research in that its longitudinal design was able to show that faster eating rates may not predict weight gain beyond a certain age (in this case, mid-life for women); this is important because it suggests that the implications may be unclear for incorporating eating rate behavior change in women over the age of 40.

Another cross-sectional study that examined the association between self-reported eating rate and BMI in a non-Asian population was published in 2017 (154). In that study, data were taken from the NQplus, an ongoing cohort study, of which 1473 Dutch adults, with a relatively even split between males and females; mean age was 54.6±11.7 years, and BMI was averaged to be 25.9±4.0 kg/m^2. Participants from the NQplus were excluded if they did not complete the SRER question, or if data were missing about their smoking status, age, education level, emotional/restraint/external eating. Participants were given a number of self-administered questionnaires, two of which contained SRER question; the time period in between the distribution of these two questionnaires was 12 months.

The researchers found that SRER was positively associated with BMI in both men and women (P=.03 and <.001, respectively), Women who reported being fast eaters had a 1.13kg/m^2 higher BMI (95% CI, 0.43,1.84) when compared to women who ate at an average speed rate (confounders adjusted for). Men were found to be SR faster eaters than women (chi square, p <0.001). Relating to the degree of agreement between the two SRER questions answered approximately 12 months apart, $\kappa = 0.64$; there was a good level of agreement between answering the SRER questions one year apart. Self-reported fast eaters were at a higher risk of being overweight when compared to slow or average paced eaters; adjusted OR = 1.73 (95% CI: 1.38, 2.17). SRER was positively associated with BMI in men and women. Energy intake was also found to be positively associated with BMI as well as with SRER.

Strengths of that study include that it was the first study to investigate associations between eating rate and BMI in a non-Asian population that included men as well as women (New Zealand study was women only) and also used objective measures to measure height and weight. Limitations included that the researchers disregarded data from 754 participants because they deemed them to be “under reporters”; however, how this was determined is not available in the published work. Overall, that study is important because it showed that self-reported fast eating rate is positively associated with a higher BMI in a non-Asian population; in this case, Dutch adults living in different regions of the Netherlands. Therefore, this research is promising in its implication that previous findings from Asian population-based research may in fact be reflected in non-Asian populations.

Eating Rate and BMI in Population Studies

Gerace and colleagues published a longitudinal study over 20 years ago that examined predictive factors of weight gain in 438 adult male fire service workers between the ages of 20 and 58 years of age (mean age in 1984 was 35.4 ± 6.6 years with an average BMI at that time of 25.8 ± 2.9 kg/m2) (5). Information was collected during physical exams at two different time points, in 1984 and 1991, including measured height and weight, physical activity levels, smoking status, and eating rate at the fire station versus all other locations, among other things. Stepwise multiple linear regression analyses were run on variables that were found to be associated with weight gain over the 7 year time period, but that were not highly correlated among themselves (5). Results demonstrated that fire fighters who reported a faster eating rate at the timepoint in 1984 gained an average of 9.9 pounds by the 1991 timepoint, compared to those participants who reported no differences in eating rate by location of meals, who gained an average of 6.8 pounds between timepoints ($p<0.006$). This early study is vital to the eating rate research in that it identified eating rate as one of a number of other potentially malleable characteristics that can contribute to weight gain, and found that those who reported eating faster at work had a significantly higher weight gain.

That study is also of interest for two reasons: first, it demonstrates that faster eating rates were associated with weight gain over time; and second, because of the population sample investigated: fire fighter personnel. This population is at a higher risk for eating fast due to the nature of their work, which may be the cause of meal interruption at any time, thereby promoting increased ingestion rate of foods (5). Other populations may be at risk, including adults with young children, people with short lunch breaks, and individuals who are provided with abbreviated lunch periods. This suggests that eating rate may be a significant potential behavior which may have a larger effect on energy intake and potentially body weight than previously considered.

Otsuka and colleagues conducted the first epidemiological study to examine not only the association of self-reported eating rate and current BMI, but its association with previous BMI from age 20 (4). In this cross-sectional study of middle-aged Japanese civil servants, 3737 males and 1005 females were weighed and measured to obtain current height and weight, and asked to report their category of eating rate on a self-administered questionnaire, based on five qualitative categories: very slow, relatively slow, medium, relatively fast, and very fast, as well as their current weight, current height, and weight from age 20. Multiple regression analyses showed positive associations between eating rate and increases in current BMI as well as previous reported BMI at age 20, and the change in BMI from age 20 to current age (4).

Limitations of this and most studies to date that collect data about eating rate include the use of self-reported eating rate. Another limitation of that study is that it was conducted in the Japanese population, which reduces the ability to generalize results to other populations including Western inhabitants. However, the large sample size, and the measurement of height and weight on this large number of participants, lend great credence to this research study. That study is important because it demonstrates significant associations between faster eating rates and obesity, both using current weight, as well as previous weight from a younger age and the change in weight from a younger age to current weight. This association suggests that there may be implications for the relationship between eating rate and weight status over time.

In a retrospective longitudinal study published by Tanihara and colleagues (6), eating rate and weight gain were explored over time in 529 male workers in Fukuoka, Japan over an eight year period. The workers received employer-provided check-ups in 2000 and 2008. Eating rates were self-reported by questionnaire, and weights were measured at both physical examinations. One way ANOVA or chi square tests were used to analyze associations between speed of eating and anthropometric and lifestyle factors; logistic regression analysis was used on the 2008 data to examine and assess the risk of fast eating for overweight (>25 kg/m^2) = odds ratios with CIs. ANCOVA was used to assess differences in weight gain between 2000 and 2008 as the dependent variable; and eating rate, age group in 2000, BMI in 2000, drinking, smoking and exercise categorical variables were used as predictors or covariates. ANOVA was used to examine interaction between eating rate, age and weight gain. Eating rate was classified into two groups (due to low number of very slow eaters) for the logistic regression, ANOVA and ANCOVA analyses: 1) fast-eating group; and 2) medium and slow eating group. The workers who reported a fast eating rate were found to have a significantly higher average weight gain when compared to the group with medium and slow eaters; weight gain for fast eaters was 1.9 kg ± 5.2 and for slow eaters was 0.7 ± 5.2 ($p = 0.008$) (6). All weight-related variables (weight, BMI and rates of overweight) demonstrated a statistically significant positive relationship with eating rate categories for both 2000 and 2008; highest values were in the fast eating group and lowest were in slow eating group. Logistic regression results showed that for the 2008 data, the odds ratio for eating rate categories for the overweight group showed a significantly high odds ratio for the fast eating group in comparison with the medium/slow eating group (OR 1.8, 95% CI 1.25-2.59). Furthermore, that study examined weight and eating rate among different age groups and found a significant increase in weight gain and % weight gain in 20-29 year olds (2.4 kg and 3.6%, respectively; $p = 0.016$) between fast and medium/slow eating groups. There were no significant differences in the 30-39 year, 40-49 year, or 50-59 year age groups.

That study is important because it was a longitudinal study that examined associations between eating rate and weight change over an eight-year period of time, and supports the findings from the previously discussed longitudinal study published in 1996

(5). It demonstrated that associations between eating rate and weight do not exist only in brief, cross-sectional snapshots of time; such relationships are in fact continuing through periods of time and faster eating rates are in fact associated with increased weight over time. In considering the age-specific results, people with a higher BMI at age 20 may continue with faster eating rate behavior, as they get older and enter middle age. These implications underscore the need to further examine the potential of teaching people to reduce eating rate as a possible longer-term mechanism to protect against the risk of developing obesity.

A systematic review and meta-analysis published in 2015 by Ohkuma et al (3) examined the association between ER and obesity. Data from 23 published studies were included in the analysis, including 20 cross-sectional studies, two longitudinal, and one with two studies; one of which was cross-sectional and the other, longitudinal. Twenty-two of the reviewed studies evaluated eating rate by self-reported measures, and one used an eating monitor. The mean values of the differences between the fastest and slowest eating categories in BMI as the independent variable, and the odds ratios for the presence of obesity as the dependent variable, were evaluated for each study. Results showed that the mean difference in BMI between fast eaters and slow eaters was 1.78 kg/m^2 (95% CI, 1.53-2.04); the pooled odds ratio of eating fast on the presence of obesity was 2.15 (95% CI, 1.84-2.51). These results demonstrate that fast eating is positively associated with obesity; in fact, the results from the examination of this group of studies suggest that fast eaters are more than twice as likely to be obese when compared to slow eaters. However, there was a high level of heterogeneity in the magnitudes of the association across studies included in this meta-analysis, as evidenced by the I squared 78.4%, $p < 0.001$ for BMI and I squared of 71.9%, p <0.001 for obesity. A reason for this heterogeneity may be that almost all of the studies used self-reported eating rate to evaluate eating rate, and these included different categories of eating rate across studies.

The use of self-report for eating rate can be considered a limitation of most research studies in this niche. However, eating rate is difficult to measure. This further supports the research gap identified, because while studies seem to consistently show a positive association between eating rate and body weight/obesity, this eating behavior remains under-utilized as a potential method of weight management. This meta-analysis concluded that further studies are needed to determine if methods to reduce eating rate might be effective for weight management (3).

In summary, the literature provides sound support and evidence for the associations between eating rate and body weight status. Faster eating rates have been repeatedly associated with high BMI and obesity. These associations withstand time, and early fast eating rates have been associated with high BMI several years later. The next portion of this review will explore the associations between eating rate and body fat as well as metabolic risk factors for diabetes and heart disease.

Eating Rate and Body Fat, Insulin Resistance and Metabolic Abnormalities

A study conducted over 23 years ago examined the relationship between body composition and daily food intake in a sample of 28 normal weight and obese Pima Indian men (mean age 29±7 years, body fat percentage 33±10%) over the course of 4 days in a metabolic unit (155). Participants had 24-hour access to vending machines that had a selection of foods available to them. The time of food selection was automatically recorded by the vending machines, and the time that wrappers and/or unconsumed foods were returned to the kitchen determined the end of the meal. Food intake and meal duration were measured by weight of food consumed by meal duration. Results showed that there was an inverse relationship between eating rate and body fat percentage; participants who ate at a slower rate tended to have a higher percentage of body fat ($r=0.61$, $p<0.01$). In fact, 37% of the variance in eating rate was found to be related to degree of obesity (155). While the methods implemented in that study certainly introduce a high risk of measurement error, the results from that study were able to suggest that the men with obesity consumed their meals on average over significantly longer period of time than participants with body fat percentages within the acceptable range ($r=0.51$, $p<0.01$). Since that study and other earlier reports from the 1970s showed inconsistent results in their investigations of eating rate in normal weight vs. obese participants, study design has improved and results can be interpreted more consistently.

An experimental study conducted in 2001 (8) examined relationships between eating behaviors and metabolic components by looking at eating rate, fat distribution, serum lipids and liver fat in severely obese participants who were scheduled for anti-obesity surgery. The participants were 30 non-alcoholic, non-diabetic, BMI women ($47\pm1 kg/m^2$) and men ($53\pm3 kg/m^2$), and the experimental design included bringing the participants in for test meal consumption while using the Universal Eating Monitor (UEM) to establish meal duration, grams of food consumed, and eating rate. Eighteen of the 46 original sample did not proceed with surgery; liver biopsy in subset of 28; 30 underwent testing with liquid meal, and 14 of those women went forward to be tested with the solid meal. Results of this testing showed that men had significantly faster eating rates compared to women, as well as higher waist-hip ratio (WHR). No statistically significant correlations between eating rate and body weight or BMI were detected, but there was a significant correlation between eating rate and WHR (r=0.47; p=0.01). When WHR was the dependent variable, in the total sample, eating rate contributed the most to the variance ($R2$=0.25, p<0.000). In looking at the subset of participants who received a liver biopsy at the beginning of their anti-obesity surgery, eating rate was positively correlated with liver fat (r=0.55; p<0.01).

Therefore, eating rate was positively associated with WHR and liver fat, but not with body weight and BMI. Strengths of that study included the unique opportunity to obtain a liver biopsy in consenting participants before the anti-obesity surgery was undertaken; also, height, weight, and blood lipids were objectively measured. Limitations include the small sample size, and the fact that laboratory conditions for test meals may not simulate real world conditions. However, that study is important because it demonstrated that faster eating rates may be associated with increased central adiposity and the presence of liver fat, which is metabolically consequential. Although the sample in that study is severely obese and candidates for anti-obesity surgery, and may not represent other populations, the results implicate that eating rate is positively associated with waist-hip ratio and the presence of liver fat, both of which are indicative of metabolic complications.

Otsuka and colleagues explored the relationship between eating rate and insulin resistance in a cross-sectional study of 2,704 non-diabetic males and females (10). Data were collected about lifestyle habits by way of a two-part self-administered questionnaire: the first part related to lifestyle habits: physical activity, smoking, and drinking habits.

The second part included the BDHQ (Brief Diet History Questionnaire) to calculate energy intake (kcals/day) using an ad hoc program in the BDHQ. Eating rate was ascertained by the question, "How fast is your rate of eating (speed of eating)?" with possible answers being very slow, relatively slow, medium, relatively fast, and very fast. The homeostasis model assessment of insulin resistance (HOMA-IR) is a surrogate marker of insulin resistance that is calculated by multiplying fasting insulin by fasting glucose/405 (156); this was used to estimate insulin resistance in these participants.

The results of that study showed that men reported eating faster than women: 50.1% men, vs. 44.1% women, reported eating very fast or relatively fast ($p<0.01$); crude BMI in men and women and energy intake in men correlated with rate of eating category; in both men and women, blood glucose, insulin and HOMA-IR increased with eating rate category. Multiple regression analysis used log HOMA-IR as the dependent variable and category of eating rate, age, and lifestyle factor as independent variables. Results showed that compared to the medium eating rate, all other categories (very slow, relatively slow, relatively fast, and very fast) increased, respectively for both men and women ($p<0.001$). After adjusting for energy intake, the results remained significant ($p<0.001$ and $p<0.01$ for men and women, respectively). After adjusting for BMI, the relationship between HOMA-IR and energy intake was no longer significant. However the relationship between eating rate and energy intake in men remained significant ($p=0.03$) but was no longer significant in women ($p=0.17$). Results did show that the women who were in the very slow eating rate category had significantly lower log HOMA-IR than those in the medium eating rate group ($p=0.01$). That study also showed a positive correlation between BMI and categorical self-reported rate of eating, and there was a significant gradual increase in insulin resistance as calculated by the homeostasis model of insulin resistance (10).

That study was conducted in Japanese civil servants, and leads to the previously mentioned lack of generalizability to other populations. However, that study is important because it demonstrates that there are associations between eating rate and BMI as well as eating rate and a reduced sensitivity to insulin, which when presented as borderline high blood glucose levels (typically between 100-125 mg/dl), is one of the factors of metabolic syndrome. Additionally, the authors address their use of SRER as a limitation, and reference the Sasaki and colleagues validation, yet report that these validation procedures may not be replicable in the current middle-aged population; therefore, more research is needed to examine the validity of this measure of eating rate.

A cross-sectional study published in 2012 examined associations between eating rate and cardiovascular risk factors including obesity (157). Participants were 7,275 Japanese men and women recruited as part of the Fukuoka Diabetes Registry study, which was designed as a multi-center prospective study to examine effects of current diabetes treatments on participants with diabetes. The purpose of that study was to examine the associations between self-reported eating rate, blood glucose levels, obesity and cardiovascular risk factors according to blood sugar levels while adjusting for potential confounders including age, sex, total energy intake, smoking status, fiber intake, drinking status and regular exercise level. Participants were divided into three groups according to fasting glucose levels and diagnoses of diabetes. There were three groups: those with normal fasting glucose levels, those with impaired fasting glucose levels (IFG), and those with diabetes. Participants were also grouped according to their self-reported speed of eating, which was obtained from the brief-type self-administered diet questionnaire (BDHQ), which contained food frequency questions about 58 items. Within this questionnaire, the speed of eating question was included: how fast is your speed of eating? Five categories as possible answers: very slow, relatively slow, medium, fast, or very fast. Very slow and slow categories were combined due to small number of self-reported very slow eaters.

The researchers found that BMI, the proportion of participants who were classified as obese, and waist circumference increased significantly with increases in eating rate categories within all glucose groups (157). The mean increase in BMI in very fast eaters when compared to slow eaters was 1.9, 2.1 and 1.5 kg/m^2 in the normal glucose, IFG and diabetic participant groups, respectively. Other findings included significant positive associations between eating rate and systolic blood pressure in he normal and diabetic group participants, and in diastolic blood pressure in the normal glucose participant group. There were also significant associations in all groups between eating rate and lipid panel values: with each increase in eating rate category, there were significant increases in triacylglycerol levels and decreases in high-density lipoprotein levels in all groups, and significant decreases in low-density lipoprotein levels in the normal glucose and diabetic participant groups (157).

Strengths of that study include the methods of data collection, in which BMI was calculated from measured height and weight, and waist circumference measurements were also obtained from trained staff and standard protocol. Additionally, experienced staff took blood pressure measurements, and blood was collected and analyzed from participants who completed an overnight fast (157). That study is critical to the eating rate body of research, because it demonstrates in a large population sample that eating rate is significantly associated with not only obesity and BMI, but also with additional cardiovascular risk factors. This is also important because the participant population contained both normal glucose participants as well as impaired glucose and diabetic participants. This sample is much more reflective of the general population in terms of prediabetes and diabetes, given the tremendous pervasiveness of these conditions; globally, the prevalence of diabetes has risen from 4% in 1980 to 8.5% in 2014; these percentages translate into 108 million in 1980, to 422 million people with diabetes worldwide in 2014 (158).

In 2012, Saito and colleagues examined associations between self-reported eating rate and BMI in a sample of 560 Japanese participants between the ages of 30-70 years with type 2 diabetes (159). This cross-sectional study also used a self-administered questionnaire to obtain information about the participants' lifestyle, including rate of eating. The questionnaire asked participants to categorize their speed of eating as slow, relatively slow, medium, relatively fast and fast; due to low number of slow eaters, combined slow and relatively slow, (new category = eating slowly) as well as fast and relatively fast (new category = eating quickly). One way ANOVAs, nonparametric Kruskal-Wallis and chi square tests were used to compare clinical variables among the groups; multiple regression analysis to explore relationship between BMI and Hemoglobin A1c with SRER after controlling for potential confounders (age, sex, diabetes duration, medication, smoking, alcohol consumption, usual physical activity, and BMI).

The results showed that BMI significantly increased along with categorical increases in eating rate (p=0.02 for ANOVA and for trend); multiple regression analysis showed that participants in the eating quickly category had a significantly higher BMI than those in the medium speed category (0.8 kg/m2, even after adjusting for age, sex, smoking, alcohol and PA cofounders; p=0.047). No significant findings were identified between HgbA1c and eating rate. Limitations in that study include that there were low numbers of slow eating rate participants (6.5% self-assessed slow eaters vs. 62.5% in eating quickly category, and 30.8% medium rate eating category). This may affect the interpretation of the findings because ideally we would like to see a more equal distribution among the groups; however, this is not practical because there seems to be a higher proportion of faster eaters in most of the eating rate research. That study is important because it was the first to examine associations between eating rate and BMI in a sample of type 2 diabetic participants; this is an important addition to the eating rate research because the findings from this study suggest that the associations that have been identified to exist between eating rate and BMI may be replicated in other populations, including those with chronic metabolic disease such as diabetes.

In 2013 Tanaka and colleagues explored associations between eating rate and body fat and insulin resistance (9). The purpose of that study was to explore relationships between participants who were considered to be “normal weight obesity,” and dietary habits including eating rate, habitual breakfast consumption and nutrient and food composition among Japanese women with a normal BMI. Normal weight obesity is defined as a healthy body weight high body fat percent (9). In this cross-sectional study, 72 female Japanese college students completed a self-administered brief-type dietary questionnaire (BDHQ), a validated questionnaire that has been used in the previously cited eating rate and insulin resistance study (10). The questionnaire included a question about usual eating rate, and the rate of eating categories = very slow, relatively slow, medium, relatively fast, very fast. Very slow and relatively slow were combined into one category, and very fast and relatively fast were combined into one category due to the small study cohort.

Results showed that there were significantly more participants in the normal body fat ratio (NBF) group who were self-rated in the slower category when compared to the number of participants in the faster category. The distribution of extra body fat ratio (EBF) was reversed, with significantly more participants self-rated in the faster eating rate group compared to the slower eating rate group. Multivariate adjusted odds ratios with 95% CI showed that participants who self-rated in the medium eating rate group were 8.16 (95% CI: 1.83, 36.44) times more likely to fall into the EBF group when compared to the slower eating rate group; those who classified as the faster eating rate were 11.48 (95% CI: 2.55, 51.72) times more likely to fall into the EBF group when compared to the slower eating rate group. Therefore a positive association was demonstrated between fast eating and higher body fat ratios (9).

Strengths of that study include that height and weight were measured, and body fat was analyzed using dual cycle bio-impedance analysis (BIA) for body fat analysis. The researchers report that this method of analysis has correlation with double x-ray analysis (DEXA) of 0.90 for men and 0.91 for women (9). Limitations include that eating rate was self-reported, but the same questionnaire was used in that study as in a previously cited study, which showed high levels of agreement between self-reported eating rate and friend-reported eating rate (7). Other limitations includes the small sample size for questionnaire-based research, and the cross-sectional nature of study prevents interpreting causality between associations. However, that study is relevant to the current review because the results show that eating faster is associated with not only higher body weight, but also higher body fat percentage (9), which is relevant to eating rate and obesity.

These studies have each contributed to the evidence supporting positive associations between eating rate and body fat percent and insulin resistance (9, 157, 159). This is worth noting because high body fat and insulin resistance are considered to be risk factors in developing cardio-metabolic issues including diabetes (158). This further lays the groundwork for the need to explore eating rate as a modifiable behavior that may be associated with reduced health risks including insulin resistance and diabetes.

Each of the cross-sectional studies cited in this review have used self-administered questionnaires for participants to complete in an effort to obtain information pertaining to the eating rate of individuals. This is the norm for the literature published to date, as it is the easiest way to obtain the information from large samples of participants. However, very few studies have attempted to validate SRER against laboratory measured eating rate. Most studies that address laboratory measured eating rate have examined the microstructural analysis of individual meals, examining eating rate at the beginning, middle and end of meals. This type of examination is beyond the scope of this review. However, what is relevant is the need to examine validation studies of SRER against laboratory measured eating rate to examine if the question used in most of the literature published to date is valid for ascertaining eating rate information. The next section of this review will explore these types of validation studies.

Eating Rate Validation Studies

A major limitation of the eating rate research is that the form of eating rate data collection in these studies was self-reported from questionnaires. However, a study by Petty and colleagues (15) compared self-reported eating rates to laboratory measured eating rates in 60 healthy male and female college students with a BMI range of 20-29 kg/m^2. Participants were selected from 1110 online survey respondents, and were observed in the laboratory eating a lunch meal using the Universal Eating Monitor, which is a validated instrument used to measure grams of food consumed over time, allowing researchers to calculate exact eating rates in this setting. Additionally, participants consumed a standardized breakfast in which they recorded the start and stop times of the meal, as well as recording their self-selected free-living snack and dinner for which they also recorded start and stop times.

For the laboratory measured meal, it was found that participants who self-reported faster eating rates ate significantly faster than those who self-reported slow eating rates; the mean eating rate of slow eaters was significantly different from fast eaters (53.0±23.6 vs. 83.0±43.6 kcals/min, p <.05). Additionally, faster eaters ate significantly faster than medium paced eaters (83.0±43.6 vs. 63.8±24.7 kcals/min, p <.05). No significance was found between medium and slow paced eaters. However, eating rate assessed by two different methods in free-living meals (calculated both in grams and kilocalories consumed divided by the unit of time as self-recorded by participants in minutes) showed no significant correlation between SRER and ER in free-living meals. These findings are important because SRER, the measure of eating rate in the literature to date, has been validated against laboratory measured eating rate using validated instrumentation and methodology. However, a research gap remains in the literature in that researchers have not been able to validate free-living eating rate against SRER, because there has not been a way for researchers to objectively collect eating rate data in free living eating situations until now.

Okhuma and colleagues' mention a preliminary study in their published paper exploring associations between eating rate and cardiovascular risk factors (157). Authors report that the preliminary study (not cited) compared lab measured meal duration to self-reported eating rate in 48 outpatient T2D patients. After adjusting for age and sex, the researchers report that meal duration was 26.1±1.9 minutes in slow eating group; 23.7±1.8 in medium eating group; 18.4±1.6 in the relatively fast eating group; and 16.8±1.9 in the very fast eating group (p for trend <0.001) (157). This is important because although they did not assess eating rate directly in their preliminary work, these authors performed validation of self-reported eating rate against laboratory-measured meal duration that demonstrated significant differences between length of time of meal among the different SRER categories.

A recent study that did perform eating rate validation was conducted by Van de Boer et al (2017) (154). That study compared SRER and laboratory-measured eating rates in 57 adults – observed eating three foods, and actual ER increased proportionately with SRER. A self-administered questionnaire on eating behavior was given to participants that included a question on eating rate ("How would you describe your eating rate compared with others?" Categories were very slow, slow, average, fast, or very fast). Actual eating rate was measured for three food products (soft bun with cheese, apple, and vanilla custard), and satiety VAS scales were completed before and after the consumption of each food. That study found that laboratory measured eating rate increased proportionately with SRER for all three food products: bread with cheese, F (1,51)=10.45, p <0.0; apple, F (1,43)=12.79, p<.01; vanilla custard, F (1,49) = 13.12. p<.01). Post hoc analyses were conducted and these demonstrated that self-reported fast eaters had a significantly higher eating rate when compared to self-reported slow and average speed eaters, but no significant differences were found in eating rate between slow and average speed eaters. Therefore, the results demonstrated that SRER was positively associated with measured laboratory eating rate.

Strengths of that study included that it was the first to assess association between SRER and lab measured ER in three foods other than pasta. However, limitations included that the serving sizes differed between participants; the researchers also excluded one participant for using a smartphone, and the foods were eaten separately. Participants also pressed a spacebar on the laptop in front of them with the first bite of the product and again when they swallowed the last; these procedures lead to concerns about the ability to simulate real-life eating conditions under these laboratory conditions. There may have been some level of distraction from having to interact with the laptop while eating. Additionally, the lunch provided 20% energy requirements based on the Schofield equation assuming a moderate physical activity level, when no information pertaining to the participants' activity levels was collected. However, these results are important to the current research for four reasons: 1) SRER was found to be positively associated with lab measured ER in three different foods; 2) there was good agreement between answers when people were asked on two occasions what their eating rate is; therefore people seem to have a good handle on categorizing how fast they eat; 3) these researchers suggest that more time should be used to investigate interventions that promote increased oral sensory time; and 4) the researchers also suggest that technologies that may aid in this type of intervention should be explored. Both of these studies underscore the need for validation of eating rate under free-living conditions, which has never been done before due to the unavailability of a valid tool to do so.

Eating Rate and Energy Intake: Systematic Review and Meta-analysis

While the literature published to date examining associations between eating rate and obesity is fairly consistent, the relationship between eating rate and energy intake is more variable. The next part of the review will examine the evidence pertaining to eating rate and energy intake. Robinson and colleagues published a well-known systematic review and meta-analysis of the literature on eating rate as it affects energy intake and hunger (13). Twenty-two studies that had an experimental design that included the manipulation of eating rate during a test meal were included in the final review; that is, the study had to have a condition in which the participants were required to consume a meal at a slower rate than an experimental condition. The studies were divided into three types: 1) those that examined the effect of manipulating eating rate on energy intake; 2) those in which participants reported hunger after meal consumption; and 3) those that examined self-reported hunger several hours after consuming a meal. Statistical analyses used in this meta-analysis were the standardized mean difference (SMD) and standard error (SE) of the standardized mean difference, which were calculated between experimental conditions for each study, and synthesized individual study SMDs via meta analysis using statistical analysis software. The SMD is a gauge of effect size: it takes into consideration the variability that would be introduced in comparing different measurement scales. It does this by measuring the difference between the two experimental conditions and dividing the difference by the standard deviation of the outcome variable for those two conditions. Pooled SMDs and 95% CIs were reported for the results of that study.

Results of this meta-analysis were as follows: for type 1 studies: Participants in the fast eating conditions consumed more energy when compared to the slow eating conditions demonstrating a small to medium effect size (SMD: 0.45; 95% CI: 0.25, 0.65; $p<0.0001$, I2 = 92%). There were three studies that compared fast, intermediate and slow conditions and in these studies, a significant difference was shown in a higher energy intake in the fast condition when compared to the intermediate condition (SMD: 0.70, 05% CI: 0.53, 0.88; $p<0.0001$, I2=35%. Between the intermediate and slow conditions, there was no significant difference. For type 2 studies: When comparing fast and slow eating rate conditions, no significant effect of eating rate was seen on the hunger outcome (SMD: 0.04; 95%CI:-0.09, 0.16; p=0.54, I2=666%). For type 3 studies: No significant effect was seen on later hunger when comparing fast to slow eating rate conditions (SMD: 0.48; 95%CI: -0.17, 1.13; p=0.15, I2=93%). Furthermore, as the eating rates were reduced in these studies, there was a larger effect size in energy intake (regression coefficient = 0.013; 95%CI:0.002, 0.025; p=0.02). This implies that with increased reductions in eating rate, there were significant reductions in energy intake (13).

The results from that systematic review and meta-analysis show that slower eating rates lead to a significantly reduced food intake, and that the mechanism for eating rate reduction did not matter, as all led to reduced intake. The results also showed that greater reductions in eating rate were associated with greater reductions in energy intake. Most studies reviewed used randomization, and no major limitations were identified although there was a significant amount of heterogeneity across studies. That meta-analysis is critically important to the current review, it summarizes the evidence that eating rate is a behavior that can be modified, and such a modification can lead to reduced intake, although more research should be conducted to explore this. For example, all studies explored in this analysis were single meal studies, which makes it difficult to the reduction in intake with eating rate modification may persist over time. There was also a lack of information pertaining to satiety in any of the studies reviewed, which may affect eating rate. Additionally, the manner in which people should be encouraged to reduce their eating rate should take place requires further investigation, because this paper reviewed studies that used several mechanisms for eating rate reduction including computerized training of individuals and the alteration of food form or texture. This is important because it highlights the need for a way in which people can reduce eating rate outside of the lab in real world conditions; this need is addressed through the work in the current dissertation.

Eating Rate and Energy Intake: Experimental and Cross-sectional Studies

The next portion of the review will consider a number of experimental studies designed to explore the effects of eating rate on energy intake. Andrade and colleagues conducted a randomized crossover design experimental study with the purpose of exploring the effect of combining three eating rate reduction techniques on energy intake and satiation (12). The techniques implemented in the study design were: taking small bites, pausing between bites, and chewing thoroughly. Thirty healthy women (mean age

22.9±7.1 years; mean BMI 22.1±2.9 kg/m^2) consumed two lunch test meals on different days, after being randomized into a slow eating condition or a fast eating condition. Participants were instructed to eat as fast as they could, while remaining physically comfortable, and were provided with a large soup spoon to consume the test meal. Under the slow condition, participants were asked to take small bites, to pause in between bites by placing spoon down each time, and to chew each bite of food 20 to 30 times. Results showed that when eating under the fast condition, the women consumed significantly more food in grams (quick: 289.9 ± 155.1 grams vs. slow: 409.6±205.8 grams), energy intake (quick: 645.7 ± 155.9 kcals vs. slow: 579.0±154.7 kcals) and water when compared to the slow eating condition. Moreover, the meal duration in the fast condition was significantly shorter when compared to the slow condition, yet satiety ratings were significantly lower in the fast condition compared to the slow eating condition.

Limitations of that study include its relatively small sample size, and the relatively healthy sample of women. This makes it difficult to generalize results to other populations such as men, those who are obese, and other more diverse populations. The test meals also took place under laboratory conditions, which makes it difficult to reproduce results in free-living environments. However, that study is key because the results demonstrate that when a slow eating intervention is implemented, it led to a significant decrease in food consumed and kcalories ingested, while invoking significantly higher satiety ratings. This is important because it shows that eating rate is a trait that can be altered fairly easily, and the results include a reduction in energy intake, which may have great implications for weight loss. Given this evidence, weight loss interventions should be explored that incorporate reducing eating rate.

The potential benefit of reducing eating rate on lowering energy intake in both normal weight and overweight groups has been explored. Shah and colleagues (2014) conducted a study that examined eating rate in a sample of both normal weight and overweight/obese participants (11). The researchers also set put to explore satiety and feelings of hunger and fullness ratings within that study to assess the effects of changing eating rate on satiation. In a randomized crossover design, participants consumed two test meals on two different occasions, after being instructed each time on how to eat the meal: participants were instructed to eat as fast as they could, while remaining physically comfortable, and were encouraged to eat as if they had a time constraint, take larger bites, and to chew quickly. Under the slow condition, participants were asked to take small bites, to pause in between bites by placing spoon down each time, and to chew each bite thoroughly. The same bowl and spoon were provided at both meals to minimize environmental effect on meal consumption.

The results of that study showed that in the normal-weight participants only, there was a statistically significant lower food and energy intake in the slow eating condition compared to the fast eating condition (p=0.04). This was not seen in the overweight/obese participants (p=0.18). During the slow eating condition, both normal weight and overweight/obese participants consumed statistically significant lower energy density (p=0.005 and p=0.001, respectively), significantly reduced energy intake rate (p<0.0001 for both), and significantly higher length of meal duration (p=0.0001 for both), when compared to the fast eating condition. These results remained constant after adjusting for age and for sex. In both groups, a significant eating condition by time effect interaction was seen (p=0.00) for hunger, fullness, desire to eat, and thirst. At 60 minutes after the meal, both normal weight and overweight/obese participants reported lower hunger ratings (p=0.01 and 0.03, respectively) in the slow condition compared to the fast condition, and the normal weight participants also rated higher fullness level in the slow eating condition compared to the fast eating condition.

Limitations of that study include the fact that the test meals were prepared and consumed in a research laboratory; therefore researchers were not able to simulate free-living eating conditions. Additionally, the mechanisms of the fast and slow eating conditions were provided to participants through instruction from the researchers, and this was not the participants' own, more natural eating rate. Finally, due to the study design, no differentiation can be made as to which aspect of reduced eating rate in the slow condition (i.e., increased chewing or pausing between bites) led to the outcomes, because these were not separated during the intervention. However, the results from that study invite the question of whether weight status is predictive of a particular response or outcome related to eating rate (for example, reduction in energy intake). That study is relevant to the current literature review because it suggests that weight status may lead to differences in outcomes relating to eating rate change.

An interesting concept in the eating rate literature is the idea that eating rate of commonly consumed foods may vary. A group of researchers from the Netherlands explored the eating rate of 45 foods that are commonly consumed, and investigated how the eating rate of these foods might be associated with energy intake (35). Thirteen men and 24 women with BMI in the normal range were recruited to test these foods in the laboratory setting. There were 7 test sessions for each participant, each taking place at the same time of day; each session had two parts, the first of which ingestion time was measured and the second of which was ad libitum food intake was measured. Ingestion time was measured by having participants press a button on a computer when they start and stop eating, and participants were instructed to eat at an ordinary pace for them, but pausing between bites and sips was not allowed. The second part of the session involved the participant being offered the same food but in a larger amount (approximately two times a large portion size of that food) and participants were told to ingest the food until they were comfortably full, and the amount consumed was measured.

Results of that study showed a positive association between eating rate and grams of food ingested when running all 45 foods Beta = 0.55, p<0.001 and R^2 of 0.50. There was an increase in grams of food intake by 4.9 grams for every 10-gram per minute increase in eating rate. Significance remained after removing semi-solid and liquid foods, and after adjusting for palatability. After adjusting for energy density of the foods, there was a small but significant positive association between eating rate and energy intake (Beta = 0.001; p<0.01, R^2=0.54). There was also a significant increase in eating rate, as expressed by grams of food consumed per minute, with increases of energy density of foods, and a small but positive association between eating rate and energy intake; for every 10 gram/minute increase, energy intake increased by 1% (35). Also, regarding macronutrient distribution within foods and how it relates to eating rate, the results showed that carbohydrate, protein and fiber content were inversely associated with eating rate (Beta = -0.012, -0.021, and -0.087, with p values of <0.01, 0.01, and 0.022, respectively, R^2=0.52).

That study is important because it was the first study to explore eating rates of commonly consumed food, and revealed large differences in eating rate between foods, as well as large variability in eating rate within food categories (i.e., solid foods). Also, it is important for practical implications because certain foods contain characteristics that place them into the category of foods with higher eating rates, and these foods are prevalent in today's society, leading to potential overconsumption of these foods. Limitations include that the lab eating conditions are artificial, especially with the participants having to press a button to signal the start and stop of each food consumed; this is not reflective of free-living conditions. Also, the study design included one session taking place immediately after the other in the attempt to have participants test many different foods within 7 sessions. That study however showed a positive association between eating rate and energy intake. That study lends important information to the eating rate literature because it demonstrates the variability in eating rate characteristics of different foods commonly consumed today, and further supports the idea that higher eating rates lead to increased energy consumption.

Eating Rate and Water Consumption

A common theme that has appeared in the eating rate and energy intake literature involves the effects of water intake on eating rate and energy consumption, as well as on appetite ratings. Previous studies examining the effects of stomach distention on satiety have suggested that water intake may contribute to this condition and therefore induce higher satiety ratings (160, 161). This was mentioned in a previously discussed study within this review, when Shah and colleagues found that there was a significant increase in water consumption in the slow eating condition in comparison to the fast eating condition in both normal weight and overweight/obese groups ($p=0.02$ and 0.03, respectively) (11).

Andrade and colleagues explored eating rate and its effects on energy intake and appetite under conditions in which water intake was controlled (162). In that study, 30 healthy, college-age women (mean BMI 22.4 ± 0.4 kg/m2, and mean age 22.7 ± 1.2 years) consumed test meals in two separate occasions with a controlled amount of water provided with the meal. In a randomized crossover design, participants consumed two test meals with one condition each: one fast and one slow, as described previously (12), on two different days separated by a washout period of 3-7 days. Participants were provided with 300 ml of water with each test meal, and were instructed in both conditions to consume the water in totality by the end of the meal. Paired t tests were used to analyze potential differences in energy intake, satiety and eating rate in kcalories consumed per minute, and within-participant repeated measures ANOVA was used to examine visual appetite scale ratings across time points and conditions.

Results showed that no significant differences were found between conditions in food consumption or energy intake. When water intake was controlled, there was a significant effect of eating rate on hunger ratings ($F[1,29]=32.72$, $p<0.001$, eta squared = 0.530) and of time on hunger ($F[1,29]=241.70$, $p<0.001$, eta squared = 0.893). Additionally, there was a significant effect of time by eating rate interaction ($F[1,29]=68.21$, $p<0.001$, eta squared = 0.702). Post hoc analysis showed that hunger ratings at 60 minutes after meal initiation were significantly lower in the slow condition when compared to the fast condition ($p=0.003$). Satiety ratings were also significantly higher in the slow condition compared to the fast condition ($F[1,29] = 10.63$, $p=0.003$, eta squared = 0.268). Limitations of that study include that the results are not generalizable to men or to women of a more diverse sample with a wider age range. Strengths included that water intake was measured prior to test meals, and water intake was measured and controlled for within the study design. Randomization of this crossover study was also strength of that study. This trial is important to the eating rate body of research because it demonstrates that inconsistent results exist in the area of eating rate and energy intake, while still supporting the association between a reduced eating rate and decreased levels of hunger with increased levels of satiety. This is critical in the large picture of eating rate research, because hunger and satiety can potentially regulate delayed energy intake, which must be considered.

Eating Rate and Within Meal Behavioral Instruction

Matsumoto and colleagues explored the feasibility of teaching women how to reduce their eating rate in two studies in which Eating Pace Instruction Classes (EPIC) were provided to healthy, overweight or obese women, in an effort to observe differences in eating rate, meal duration, and energy intake (47, 48). The first study investigated the effect of an individual within-meal eating behavior intervention in which the participants, who were 23 healthy women (mean age 20.0±2.6 years, and mean BMI 31.8±2.6 kg/m2), were randomly assigned to an intervention or a control group. Before and after the intervention, the participants consumed an ad libitum test meal. Participants randomized to the treatment group received one-on-one instruction about reducing eating rate by pausing between bites, placing spoon down between bites, and chewing food 20-30 times per bite. Researchers observed the test meals, and the start and stop times of the meal and food consumed were covertly measured using a Universal Eating Monitor. Repeated measures ANOVAs were run to assess within-participant differences, and results showed that participants who received the intervention significantly decreased their eating rate ($p=0.032$) and energy intake ($p=0.022$) (48). In another study, this within meal behavior instruction was tested at the group level, under similar study design conditions with the exception of the instruction being provided to a small group of 29 healthy, overweight or obese women (mean age 21.1±4.4 years, and mean BMI 31.0±2.7 kg/m2). Results from this intervention demonstrated that the EPIC intervention significantly reduced eating rate of the women ($p=0.009$) and increased the time duration of the meal ($p=0.005$); energy intake decreased after the intervention, but this did not reach significance (47).

This research is important to the current review because it demonstrates that eating rate is a specific trait that can feasibly be changed through instruction, both at the individual and group levels. This is critical to the current research because while an effective intervention has been identified, this level of intensity in instruction is not scalable to large populations. Furthermore, there is a research gap that exists in the missing literature that could explore the direct relationship between reducing eating rate and weight loss. These two key concepts have not been linked to date in the currently available literature. Moreover, in order to implement such an intervention to effect weight loss, there is a need to have a way to monitor free-living, or more realistic, longer term eating rate monitoring, which that which has been conducted thus far in the eating rate literature by way of laboratory test meal measurement. A novel device, the Eat Less, Move More (ELMM) device, may be a potential connection for these relationships and provides a way in which useful self-monitoring, goal setting and feedback can be woven into reducing eating rate, potentially reducing energy intake, and providing a path to weight loss and healthy weight management.

To date, the ELMM device has been used under laboratory conditions to count bites and provide bite count feedback to the user of the device. In a study published in 2011, Scisco and colleagues examined the effect of a new device that is capable of counting bites, on slowing down bite-rate and subsequent energy intake in the laboratory setting (28). In that study, 36 college age students (mean age19.7 ± 3.5 years, and mean BMI 25.04 ± 6.49 kg/m^2) participated in a study in which they consumed a test meal under three conditions while wearing a sensor on their wrist and consented to being videotaped during the meal. The conditions were as follows: in the baseline condition, participants were provided with bite-size pieces of the test meal and instructed to until they were comfortably full, by consuming one bite at a time to allow the researchers to control for bite size. While participants ate, they were covertly observed by the researchers who pressed a compute key to record each time the participant took a bite. The next time the participants came to the lab, the same condition applied with the exception of the participants being able to see the computer screen, which displayed their bite feedback. Finally, in the third visit, participants were asked to maintain a reduced bite rate as shown on the computer screen by a red line, which represented a 50% reduction in bite rate from the original baseline rate. The researchers hypothesized that participants who consumed a greater amount of energy at baseline would reduce their energy intake after a bite-count manipulation intervention.

Repeated measures analysis of variance showed an overall significant difference in energy intake across conditions ($F[1.61,46.62]=4.10$, $p<0.05$, eta squared = 0.12).

Compared with the feedback condition (mean = 428.2±201.3 kcalories), participants consumed a significantly reduced amount of food in the slow-rate condition (mean = 357.8±176.8 kcalories, $t(29)=-3.54$, $p<0.05$). There were no significant differences seen between conditions in satiety ratings or water consumption. Post hoc analyses were run to examine the effect of the intervention on energy intake, and results showed that high baseline energy consumers who ate more than 400 calories showed a significant decrease in energy intake in a slow bite-rate condition (mean = 453.3±130.4 kcalories) when compared to baseline (mean = 616.9±200.2 kcalories, $t(10)=-3.84$, $p<0.05$) and feedback conditions (mean = 594.9±145.10 kcalories, $t(10)=-3.45$, $p<0.05$) (28).

Strengths of that study include the ability to control for bite size under laboratory conditions. However, these conditions also can be viewed as a limitation in that laboratory conditions do not adequately simulate free-loving conditions, which are necessary to investigate the effects of an eating rate intervention for a longer period of time that that allowed for one test meal. This research is key because it is the first step in considering the effects of a wearable device that can count bites as a way to control energy intake through bite rate manipulation. Although the sample sizes of these studies were small, significant changes were detected in laboratory-measured eating rates and energy consumption as well as meal duration. These interventions provide support for sample size/power of the current dissertation research.

In summary, the emergent themes in reviewing the published eating rate literature can be summarized into three parts. The first concept is that SRER has been positively associated with higher BMI and obesity, as well as higher body fat percentage and insulin resistance. The second concept is that studies examining eating rate and energy intake are inconsistent, but more recent publications point to a positive association between eating rate and energy intake. This is significant, because the research has also shown that the manipulation of eating rate through effective training to reduce it has led to decreased energy intake. Given the relationships between eating rate and obesity, as well as eating rate training leading to reduced energy consumption, the logical next step in this realm of research should be examining manipulations of eating rate within a weight loss intervention. Finally, the research shows that self-reported eating rate is the standard for obtaining this information from participants. While two small studies to date have validated this self-reported measure of eating rate, both of these validation studies have been done in using laboratory measured test meals. A gap that currently exists in the literature is information pertaining to validation of free-living eating rate, due to the inability to effectively measure this metric. It would be beneficial to the eating rate body of research to examine the validity of the ELMM device as a way to validate free-living eating rate data.

Self-Monitoring as a Behavioral Intervention in Weight Loss

The following portion of the literature review will explore the role of self-monitoring in weight loss, presenting evidence for this behavioral intervention as an effective tool to help individuals in achieving weight loss outcomes.

Of the many behavioral interventions explored and implemented in weight management, self-monitoring has been consistently associated with weight loss. Self-monitoring in this context has been defined as recording dietary intake and physical activity in an effort to increase awareness of current behaviors (16). Self-monitoring is a key component of successful weight loss, and the significance of self-monitoring behaviors in weight loss has been established (17-19). Many interventions that have utilized self-monitoring have been successful in helping individuals achieve reduced energy intake, increased physical activity, and weight loss outcome goals (18, 163-167).

In 2013, the American Heart Association and the American College of Cardiology, along with the Obesity Society, published the Guideline for the Management of Overweight and Obesity in Adults (115). In this publication, behavior therapy was presented as a key component of high-intensity lifestyle interventions for weight loss. To achieve and maintain weight loss, a structured behavior change program in which consistent self-monitoring of dietary intake, physical activity, and weight has been recommended by the expert panel (115). The following sections will discuss self-monitoring of dietary intake and physical activity, followed by adherence of self-monitoring behaviors, and goal setting and feedback as adjunct therapies to self-monitoring.

Self-Monitoring of Dietary Intake

A systematic review of the self-monitoring in weight loss literature published in 2011 outlined recommendations obtained from 15 studies in which food intake was self-monitored (22). Significant associations were found between self-monitoring of dietary intake and weight loss. A more recent study aimed to identify specific contributors to weight loss demonstrated that self-monitoring of a number of weight-related behaviors was shown to predict weight loss (20). This retrospective analysis found that tracking and recording dietary intake at least three days per week was one of the self-monitoring behaviors that was significantly related to weight loss at 6 months (20). A secondary data analysis published in 2017 explored relationships between the frequency of self-monitoring dietary intake with a smartphone application and weight loss, and found that participants who self-monitored dietary intake most often had more weight loss (21). These findings suggest that self-monitoring is associated with weight loss, and increased frequency of this behavior leads to more successful weight reduction outcomes.

Accuracy in Self-Monitoring of Dietary Intake

Lack of accuracy is also an aspect of self-monitoring that should be addressed. Traditional means of recording and tracking dietary intake have been effective, but these can be burdensome and often require a substantial amount of time and effort. This burden, along with lack of knowledge about foods and portion sizes, may contribute to a decrease in accuracy of self-recorded food intake records, in which intake is typically underreported by 4-37% (168). Additionally, underreporting is more prevalent in overweight compared to lean individuals (169). Often, individuals who are overweight are more likely to attempt weight loss, and it is important to ensure that self-monitoring methods are accurate. interventions requiring recording of dietary intake. A study that compared two methods of dietary self-monitoring in young women showed that food records completed through computer-based or smartphone based technology were found to be more acceptable when compared to paper-based food diaries, and that the accuracy of the two methods were similar (170). However, even these forms of tracking that have emerged in popularity still require time and knowledge of the user relating to food types and portion sizes. There is a need for scalable behavioral interventions to promote weight loss with accurate, user-friendly, dietary self-monitoring tools that will assist in weight loss but not require a lot of time or effort.

Self-Monitoring of Physical Activity

The American College of Sports Medicine (ACSM) recommends that adults get 150 minutes of moderate-intensity physical activity per week (171). Physical activity is a clinically accepted approach to weight loss; however, many people fall into a low or sedentary physical activity level. In 2014, only 21% of adults in the US met the recommended levels of physical activity (147). Weight loss and increases in physical activity have been strongly linked to the reduction of risk factors for chronic disease, including diabetes mellitus, cardiovascular disease, and several types of cancer (172-175). Additionally, cardiorespiratory fitness has been shown to significantly decrease cardiovascular disease risk factors (176). Moderate intensity lifestyle activity was found to be associated with improvements in cardio-metabolic risk factors, including diabetes and high cholesterol (177, 178). Recommendations to increase physical activity levels have been issued by public health authorities including the Centers for Disease Control and Prevention (CDC) and the ACSM (179). However, much of the largely sedentary US population has failed to meet these recommendations in spite of evidence for improved health and reduced disease risk factors (180). Low levels of physical activity have contributed to the obesity epidemic in the US (181).

According to the Position Paper from the ACSM, the importance of self-monitoring in exercise has been well established (171). Technology may play a role in improving the physical activity habits of many people, as evidenced by the growing popularity of smartphone application and wrist-worn wearable devices that track steps and estimate calorie expenditure with reasonably accurate approximations (182, 183). Trends in the fitness industry have shown the popularity of accelerometers in self-monitoring physical activity, another important aspect of weight reduction and decreased cardio-metabolic risk (177, 184). Passive monitoring of physical activity is available through various activity monitors and applications. In a study of 40 adults with obesity, consistent self-monitoring of exercise was positively associated with greater exercise, fewer difficulties with exercise, and greater weight loss (167).

Current evidence suggests that dietary and multi-component interventions are more effective in targeting overweight and obesity when compared to singular interventions (for example, dietary monitoring only) and physical activity interventions alone (185). Pourzanjani and colleagues examined the use of digital health trackers which were used by people seeking weight loss, and found that people who tracked activities more often tended to lose more weight than those who tracked less often (186). However, that study did not explore the time necessary to manually track activities by participants. A recent focus group-based study focusing on barriers to weight loss found that people who were seeking weight loss desire goal-setting and technology that provides motivation for weight loss and increasing physical activity (187).

Adherence to Self-Monitoring Behaviors

In reviewing types of dietary self-monitoring, there are many available including a mix of recording exercise, mood, and eating situation among other variables that affect energy intake and expenditure (22). Even after consideration of the importance of self-monitoring in weight management interventions, it has been established that self-monitoring adherence tends to decline over time (22). Research has shown that regardless of the type of self-monitoring - for example, paper based record keeping versus technology-based tracking through personal digital assistants or smartphones - the level of adherence to the activity of self-monitoring appears to have a greater impact on the success of weight loss outcomes than the type of self-monitoring (188). A study that compared the use of a personal digital assistant to self-monitor dietary intake to previous results in which participants used paper diary tracking method showed no advantage of the software-based self-monitoring, and weight loss was similar between groups; furthermore, more frequent self-monitoring of intake in both methods was positively associated with weight loss (189). As more ways in which individuals can track their behaviors have become available, a subsequent improved adherence to self-monitoring behaviors is often accompanied by improved weight loss outcomes. A study that investigated self-monitoring over 12 months as one component of a behavioral weight loss program demonstrated a decline in all treatment components of the intervention; furthermore, adherence to exercise was significantly associated with weight loss (190).

Self-Monitoring with Goal Setting and Feedback

Scientists who have examined the role of self-monitoring in relation to weight loss have employed a variety of tools. Self-monitoring coupled with goal setting and feedback has been shown to effect positive change in health behaviors (191). Goal setting has also been identified as an effective tool in weight loss (192). These behavioral interventions, when used together, may provide opportunity for individuals to identify a targeted behavior or indicator of health, and then employ behaviors to track progress toward achieving that target. In a study conducted by O'Donnell and colleagues, the role of goal setting within a 10-week online intervention designed to promote fruit and vegetable consumption and decrease the decline in physical activity in young adult college students (191). Findings from that study demonstrated that participants who achieved their goals more frequently had greater improvements in behavior change in the form of increased fruit and vegetable consumption and physical activity (191).

A computer-based self-monitoring feedback system for improving adherence to diet, exercise and weight loss outcomes was examined through the POUNDS LOST study, which was a randomized controlled trial(193). In that study, when compared to those who used the program less frequently, participants who had more frequent usage of the self-monitoring and feedback system had significantly greater weight loss after 32 weeks (193). A more recent study aimed to identify differences in self-monitoring consistency between participants who were randomized to a basic web-based self-monitoring program for weight loss or a program with the same self-monitoring tools as well as enhanced, individualized feedback on self-monitoring. That study found the consistency of self-monitoring tool use was significantly greater in the enhanced feedback group, for both food intake and exercise; additionally, greater consistency in self-monitoring was significantly associated with greater weight loss (194). These studies suggest that the addition of goal setting and feedback enhances the self-monitoring aspect of behavioral interventions targeted at weight reduction, and such additions are associated with greater success in weight loss outcomes.

Self-Monitoring and The Eat Less, Move More Device

The Eat Less, Move More (ELMM) device is wrist-worn and has the ability to track bites taken as well as eating rate of foods ingested (24, 195). A new feature of the ELMM is that it contains a tri-axial accelerometer, and is now also able to track the number of steps taken by the user (60). The ELMM is unique in that it is the only wearable device that can measure both food intake and energy expenditure without record keeping or calorie counting (60). The need exists for systems through which people can self-monitor both eating and physical activity behaviors. The ELMM device has the ability to provide a mechanism for self-monitoring, goal setting and feedback of food intake and physical activity. This technology may have the potential to help individuals improve eating behaviors as a means to aid them in self-monitoring behaviors by tracking bites, eating rate and steps, in an effort to assist in weight reduction efforts.

The Bite Counter/Eat Less/Move More (ELMM) Device

Bite Counting as a Weight Loss Approach

Many types of weight loss interventions exist, and many incorporate a function of self-monitoring food intake (22). Historically, paper food diaries were used to record intake, and more recently, smartphone applications for weight reduction allow individuals to track intake (21, 22, 196). Counting bites is a relatively new concept in weight loss, and the potential for reducing bite count as a mean to weight loss has been proposed (25, 197) In 2015, a pilot study examined the feasibility of bite counting and percentage-based bites reduction as a weight loss approach (197). Sixty-one participants were asked to count and record bites for one week; after this week of baseline bites was established, participants were asked to adhere to a goal of a 20-30% reduction in the number of bites. Participants who completed the five-week intervention lost a significant amount of weight (mean 1.6 kg, $p<0.0001$). Although this is promising, the limitations of this particular study are significant: the attrition rate was higher than average, with only 41 participants (67.2%) completing the study, and a completer's analysis was used. The reporting of number of bites consumed of foods and caloric beverages was entirely self-reported, in that participants counted their own bites and were then responsible for emailing or texting the number of bites to the researchers. The study also lacked a control group, and the follow-up period was relatively short at 5 weeks.

The Device: Functionality and Accuracy in Laboratory Settings

The Eat Less, Move More device, formally known as the Bite Counter in its earliest form, is a new device that is worn on the wrist like a watch and displays the time when not in use. It has a built-in micro-electro-mechanical gyroscope, which, with the use of an algorithm, is able to detect wrist-roll motion and track hand-to-mouth motions, thereby detecting and recording when an individual has taken a bite of food (23). In a study published by Dong and colleagues in 2012, two in-laboratory experiments were designed to explore the validity of this device in terms of its ability to evaluate the accuracy of the device to identify bites, and one out-of-laboratory experiment was designed to explore the correlation of the bites that are detected by the device with kcalories consumed (23).

The first two experiments involved participants consuming a meal while wearing the prototype device on their dominant hand. The sensor within the prototype was wired to a computer. In the first experiment, 51 participants were monitored eating a total of 139 meals while wearing a prototype version of the device. They were instructed to eat the test meal provided one bite at a time and to not converse with the experimenter or use the hand with the device to drink or use a napkin. The second experiment involved 47 participants consuming a total of 49 meals, while wearing both the prototype sensor as well as a smaller version of the sensor, both of which were mounted to a wrist-worn package (23). A video camera was mounted a few meters from the participant to establish ground truth measurement of the ability of the device to detect bites. Participants were served a test meal, and were observed by researchers under both conditions. Results showed that out of 139 meals observed, there was a 94% sensitivity of the device in detecting bites, with 6% of the bites observed by researchers remaining undetected by the device (23). When considering the results of the two different types of sensor measurements, the sensitivity of the prototype sensor was 85%, and the smaller *STMicroelectronic* version was 86% (23).

In the third experiment, the researchers sought to examine whether a correlation exists between bites taken by participants and kcalories consumed. Four participants wore the device outside of the laboratory setting for a total of 54 meals, in several real-world situations of eating including home meals, meals consumed at work, meals in restaurants, and eating in a social situation. The participants kept written food logs, and the researchers estimated kcalorie consumption based on these food logs. A moderate positive linear correlation was found (R=0.6) between bites taken and kcalories consumed. These results demonstrate the feasibility of this device to work inside and outside of laboratory conditions for the purpose of detecting bites, as well as the ability of the device's bite count to be correlated with kcaloric intake.

In the same year, the validity of the device was explored in the laboratory setting. Fifteen participants were asked to consume a several different foods within one meal lasting approximately 30 minutes, using their hands to eat some foods and various utensils for other foods, while wearing the Bite Counter (198). The researchers covertly observed the participants consuming the foods through a one-way mirror, and manually tracked the number of bites taken by each participant. Statistical analyses compared the manually tracked number of bites to those tracked and recorded by the Bite Counter. Results showed that the validity of the device varied based on the type of food; device was shown to underestimate some foods (i.e., soup eaten with a spoon produced a 40% underestimation of bites by the device), while overestimating bites of other foods (i.e., a 27% overestimation of bites was seen in the consumption of meat with a fork and knife).

There were no statistically significant differences between manually tracked and device recorded bites with the hand-held foods (i.e., pizza).

Limitations in the functioning of the device that were identified by that study included that for participants who ate rapidly, the device failed to detect some of the bites taken; additionally, participants at times “locked their wrist” when eating soup, presumably so as to not spill it, and this also led to decreased detection by the device (198). However, although the validity of the device in this laboratory setting varied according to category of food, the ability of the device to measure a mean of 81.2% bites taken was demonstrated (198). This is comparable to more traditional means of tracking intake (29, 169, 199). Additionally, a later study (24) provided information relating to the speed of eating in a cafeteria setting, which was faster when compared to the original testing of the device within a laboratory setting (23). Therefore, the creators of the device were able to improve the minimum time between bites from 8 seconds to 6 seconds (24). That study is critical to the Bite Counter research, because it established what is known as the ground truthing process for this device (24).

Comparison of Bite Counter-Based vs. Human Estimation of Calorie Intake

Salley and colleagues took the accuracy investigation of the Bite Counter’s into an important next phase when they sought to compare the individualized bite-based measurement of kcalorie intake to participant-measured kcalorie intake (200). Two hundred eighty participants were invited to consume a test meal in a cafeteria setting, and were randomly assigned to two groups: those who were provided with the kcalorie information of the foods they consumed after the meal, and those who were not provided with this information. Participants were allowed to choose from a wide variety of foods and were instructed that they could eat as much as they wanted. Participants consumed their test meals at tables, which were instrumented with tethered Bite Counter devices, and meals were video recorded. Researchers who were trained in estimating portion sizes of foods, and who demonstrated strong inter-rater reliability, recorded the amounts consumed by participants. From this information, kcalorie intake of each meal was estimated. After the meal, participants were asked to estimate the number of kcalories they had just consumed; participants in the kcalorie information provided condition were given this information, while those who were randomized to the group with no kcalorie information did not have access to this information. The researchers also calculated an estimated kcalorie intake per meal identifying the number of bites detected by the tethered Bite Counter device, and multiplying the total number of bites by each participant's estimated kcalories per bite as determined using demographic and physical characteristics including height, weight, waist-hip ratio, sex and age.

The estimations determined by the participants in both the kcalorie information provided group and no information provided group were compared to their actual intakes as identified by the researchers' estimations, and subtracting their personal estimations from researcher-recorded intake identified participant error. Participant estimation error between both conditions was compared, and results showed that there was a significant difference between the two groups, with the participants who were provided with kcalorie information having significantly less error than the group with no kcalorie information ($t[220.358]=12.078$; $p<0.05$). Both groups tended to underestimate their kcalorie intake, which is consistent with previous literature (199, 201). A comparison between the bite-based method of estimating kcalorie intake and the better of the two human estimation conditions (in this case, the group with provided kcalorie information) showed that the estimation error for the bite-based method was significantly lower ($t[67]=-3.683$; $p<0.001$). Additionally, there was a smaller range of error of estimation in the bite-based method group compared to the human estimation method (200). There was no main effect of BMI on bite-based information ($F[2, 129]=.436$; $p=0.0648$), and no relationship between BMI and bite-based estimation error ($r=-.115$; $p=0.0186$).

That study is important because it demonstrated that when people are provided with kcalorie information, they are able to make more accurate estimations of their kcalorie intake. The study then showed that when comparing this condition to the newer bite-based estimation of kcalorie intake, the bite-based method had significantly less error in estimation (200). That study is also important to the newly established Bite Counter body of research because it contributed new information by creating a regression equation model that identified specific participant characteristic-related predictors of kcalorie intake per bite. Limitations of that research study included that no variables relating to the food types chosen and consumed went into the regression model used to predict kcalorie intake. Additionally, variables of height, weight and WHR were used in the model in spite of their low predictive value as identified in these analyses; this was done based on the researchers' contention that these variables may in fact be predictive of kcalories per bite intake based on previous literature. However, in spite of these limitations, that study is important because it added a critical step in the ability to move bite-measured intake into the weight loss area, because it provides the missing connector between bites taken and kcalories consumed.

Bite Counter and the Effects of Feedback and Goal Setting

Jasper and colleagues conducted two studies to examine the effects of the Bite Counter on eating behaviors as well as the effects of the Bite Counter coupled with a bit goal on eating behaviors (202). In both studies, participants were randomized into either a group in which the test meal was served on a large plate, or a group with the meal on a small plate. In the first study, 94 participants were recruited to consume a test meal in the laboratory and randomized into either a Bite Counter group or no Bite Counter during the test meal. In the second study, 99 participants were recruited and all wore the Bite Counter during the test meal, but in addition they were randomized into either a group who received a low bite count goal, or a group with a high bite count goal. Participants were provided with a serving utensil and were allowed to serve themselves *ad libitum* (202). Analyses of variance were run to determine the effect of plate size (large vs. small), the presence of feedback (Bite Counter or no Bite Counter), and type of goal (low vs. high) on consumption.

Results showed a main effect of plate size, in that participants eating from the large plate had significantly greater food intake ($F[1, 90]=11.375$; $p=0.001$) and greater number of bites ingested ($F[1, 90]=11.644$; $p=0.001$); feedback receivers consumed less grams and took fewer bites. There was also a main effect of feedback on consumption, as participants who wore the Bite Counter during the meal consumed less than those without the Bite Counter ($F[1, 90]=6.089$; $p=0.011$), and took fewer bites ($F[1, 90]=15.051$;

$p<0.001$). No interaction of plate size and presence of Bite Counter was detected. Regarding the second study, a main effect of plate size was seen again, with those participants eating from the large plate consuming more than those with the small plate ($F[1, 95]=9.029$; $p=0.003$). There was no effect of bite count goal on consumption between the two plate size conditions. Results revealed that there was a main effect of goal on number of bites taken ($F[1, 95]=27.691$; $p<0.001$) in that participants who received the low bite goal took significantly fewer bites than those in the high bite count goal group. No effect of plate size, or interaction of plate size with bite goal, was detected in these analyses. That study also explored satiety ratings within test meal consumption, and revealed that there was a main effect of goal on bite size ($p=0.003$), serving size ($p=0.023$), postmeal satiety ($p<0.001$), and satiety change ($p=0.001$). This demonstrates that participants in the low bite goal group served themselves more, took larger bites, and reported lower satiety levels after the meal with lower levels of satiety change from pre- to post-meal (202).

These studies are important because they are the first to consider the addition of a bite count goal to the bite count feedback that is provided to participants wearing the device. The results also suggest a compensation effect of bite size when participants know that they are being asked to limit their bite count, because even though the low bite count goal group took a significantly fewer number of bites, the consumption in terms of grams of food consumed did not change. In addition, these participants reported feeling less full, which brings into question the effects of decreased satiety on consumption after and outside of the test meal. The results of these studies demonstrate that there is a need for more work surrounding the effects of bite measures, goal setting and feedback.

The Device and Accuracy in Less Controlled and Free-Living Settings

Extending the work done in the previous two studies, and in order to explore the accuracy of the device, Scisco and colleagues examined the Bite Counter in free-living settings (25). Seventy-seven participants were enrolled in that study in which they wore the Bite Counter for a total of two weeks. Participants also completed an online self-administered dietary recall (ASA24) each evening throughout this time period. Pearson's correlations were run to examine associations between device-recorded bite count and ASA24 estimated kcalorie intake. Dependent t tests were used to examine the self-reported use of both the Bite Counter and the ASA24 website as a means to record intake. Results of that study showed that over 2,975 eating activities recorded, there was a significant positive correlation between bite count and ASA24 estimated kcalories (r = 0.44; p<0.001). The average within-individual correlation between bites taken and kcalories consumed was 0.53, a moderate correlation (25). This information is a significant contribution to the literature, because it is the first piece of evidence supporting an association between bites taken and energy consumed, which is a critical connection as the application of this device enters the weight loss realm of study. That study also identified differences between males and females in kcalorie intake per bite, with males consuming an average of 6 more kcalories per bite than females ($F[1,71]=14.38$; $p<0.001$, $\eta^2=0.17$). That study contributed new information to the Bite Counter body of research by demonstrating that bites are moderately correlated with kcalorie intake, and that the kcalories per bite significantly differ between males and females. In examining the participants' ratings of the ease of use of both of these tracking modalities, participants reported that the device was significantly easier to use in comparison to the website for recording intake ($t[76]=8.72$; p0.001). In addition, 57 of the 77 participants reported that they preferred to use the Bite Counter to the ASA24 (25).

Aside from this two-week experimental study exploring the accuracy of the device in free-living settings, most of the studies conducted in this area utilize tightly controlled laboratory settings and scripted eating activities, which is a limitation in the previous Bite Counter research. Although laboratory controlled research is critical to control the types of foods consumed, in an effort to gain insight into the device's accuracy of bite detection, it lacks the ability to create a more natural environment and increase the variability of types of food offered to a more diverse population in terms of sex, age and ethnicity (24). In 2016, Shen and colleagues, identified this limitation and sought to test the accuracy of the Bite Counter across demographic and food variables (24). This group of researchers recruited 276 participants to come to a cafeteria setting, select from a wide variety of food types, and consume the foods in this more natural environment (24). Participants were asked to sit at tables with three other participants, and wear two *STMicroelectronic* sensors within one device to detect wrist motion while consuming their selected foods. Participants were covertly videotaped while eating and interacting with other participants. Researchers then watched the recordings through a custom-made program designed to allow the researchers to manually label ground truth bites. This custom program was also able to determine agreement between raters on when the bites occurred as well as what food was consumed, whether participants used their hands to eat or a utensil; raters also determined which type of utensil was used (24).

Results of these demonstrated a 75% sensitivity in detecting bites across 24,088 bites taken in that study. These results contributed valuable information; that the speed of eating in this cafeteria setting was faster when compared to the original testing of the device within a laboratory setting (23). Therefore, the creators of the device were able to improve the minimum time between bites from 8 seconds to 6 seconds (24). That study is critical to the Bite Counter research, because it established what is known as the ground truthing process for this device (24). This time-consuming method of assessing the accuracy of the Bite Counter in detecting bites in a more natural setting, with a sample of 276 participants, selecting from 374 different food choices, certainly lends increased credibility to the use of the device in a less controlled experimental setting. The detection of 75% of bites taken in this setting lays the foundation for the next steps in this research area, which include exploring the application of the device in more free-living settings.

A more recent study by Turner-McGrievy and colleagues published in 2017 explored the role of the Bite Counter in weight loss (60). In that study, participants were asked to attend a baseline orientation visit, during which they completed questionnaires, including a demographic questionnaire, as well as a self-administered physical activity questionnaire (IPAQ) and self-administered 24-hour dietary recall (ASA24). Height and weight were also collected during this visit. The 81 adult participants (mean age, 48.6 ± 11.7 and 47.5 ± 12.3 kg; mean BMI 33.4 ± 4.8 and 33.4 ± 5.7 kg/m^2 for the app participants and for the Bite Counter participants, respectively) were then randomized into one of two groups. The first group (n=42) utilized a traditional mobile app as a means to track intake, and the second group (n=39) used the Bite Counter device as a way to track intake. Both groups received the weight loss intervention, which was twice weekly podcasts over the course of 6 months. Seventy-five percent of the participants completed study after 6 months, and an intent to treat analysis was done. Weight, physical activity and energy intake, as well as usage of tracking system (app or Bite Counter) were assessed at 0, 3, and 6 months. Chi square tests revealed that both groups had significant within-group weight loss, and when considering between-group comparisons and repeated measures models, the app group had a significantly higher weight loss than the Bite Counter group (-6.8 ± 0.8 kg vs. -3.0 ±0.8 kg, p<0.001) at the six-month mark. Regarding physical activity, the Bite Counter group significantly increased their metabolic equivalent energy expenditure (+2015.4 ± 684.6 METS/min/week) compared to the app group (-136.5 ± 630.6 METS/min/week, p=0.02) at the 6-month mark.

That study has many strengths, as it compared two active methods of self-monitoring for weight loss over the course of 6 months. Although anthropometric and dietary and physical activity questionnaire data were collected at baseline, three months and six months, the intervention was remotely delivered in that participants did not have communication with the researchers as they continued their use of the self-monitoring methods. Regardless of the method, there was a significant correlation between number of podcasts downloaded by participants and number of days tracked, and weight loss (r = -0.33, P < 0.01 for both). This is important to the body of Bite Counter device research that is accruing, because this evidence suggests that adherence to self-monitoring intake is associated with weight loss. Other strengths of that study include that the researchers were able to objectively monitor the usage of the main intervention and dietary and bite counter usage. Limitations of the study include the use of self-reported dietary and physical activity data, the quality of which may be affected by under- or over-reporting; another limitation is that it is unclear how participants were able to decrease bite goal if weight loss was less than 0.5 pounds per week. Another issue with that study is that days of tracking with any food entries into the app or any bites recorded were considered to be a day of use for the app or device. This could include days in which participants took only one bite or recorded only one food consumed. However, the results clearly demonstrate that the use of a self-monitoring app or device can lead to significant weight loss.

A recent study that investigated the use of dietary self-monitoring with the ELMM device in a 4-week weight loss intervention did show weight loss in a group of 12 participants with overweight or obesity (61). In that study, the participants attended weekly one-hour group sessions run by a registered dietitian, who was experienced in health behavior and weight loss training. Participants were provided with a kilocalorie per bite goal, and if weight loss did not occur each week, were provided with a lower bite goal (61). In addition, weekly topics were covered in the group sessions, including goal setting and increasing intake of fruits and vegetables. Participants also received weekly challenges such as using a provided kcalorie per day limit, and also downloaded biweekly podcasts used in previous weight loss studies (59, 203). Results showed a significant weight loss (-1.2, ± 1.3 kg, $p<0.05$) and use of the device was significantly correlated with weight loss ($r= -0.58$. $p<0.05$) (61). There were also improvements in weight management behaviors as measured by Eating Behavior Inventory. However, it is difficult to know if the weight loss or behavior changes were the result of the device use, as there were multiple supplementary aids built into the study design. In addition, the sample size of 12 participants was small, and the study design lacked a control group to compare between group differences.

In summary, the Bite Counter, which has progressed to the Eat Less, Move More device shows promise in its ability to offer passive, wearable self-monitoring to individuals. The device has been validated in bite count (25), and the ability to estimate kcalories per bite has been noted (200). The device has continued to improve in its accuracy, is now capable of tracking second per bite (SPB) as a measure of free-living eating rate (24), and has been rated as easy to use (61). Next steps should be to assess its effect on body weight and eating rate within a weight loss intervention with a control group, as well as explore validation of its efficacy in tracking eating rate.

Metabolic Adaptation

Metabolic Adaptation in Weight Loss

As critical as the achievement of weight loss to reduce obesity and its associated comorbidities is, consideration must be given to the importance of weight maintenance. One key concept that has been associated with the ability to maintain weight loss is adaptive thermogenesis, otherwise known as metabolic adaptation. Metabolic adaptation is defined as a reduction in RMR (RMR) as a result of weight loss, which is greater than would be expected based on the amount of weight lost (87, 88). This phenomenon has been well documented in the literature; in the presence of a negative energy balance, RMR decreases further than would be expected from reductions in body mass and changes in body composition (87-89). Furthermore, the existence of this state likely contributes to the difficulty of obese individuals to lose and maintain a healthier weight (87, 90).

Total energy expenditure consists of approximately 60% RMR, which encompasses all metabolic processes including the cardiopulmonary, liver and kidney functioning of the body; approximately 10% from the thermic effect of feeding; and the remaining is attributed to the more variable energy expenditure from physical activity (204). RMR is largely affected by the presence of fat free mass (205). The following section will address the existence of metabolic adaptation as demonstrated in the literature, first by review and then with evidence from experimental studies.

Metabolic Adaptation

One of the first and most noteworthy landmark publications that revealed the effects of metabolic adaptation was published by Ancel Keys and colleagues, in their revelation of the effects of semi-starvation on men in the Minnesota experiments from 1944-1945 (206). These experiments aimed to describe the physiological and psychological effects of semi-starvation during the ending of post-World War II, when researchers sought information on how to best aid those who had been exposed to starvation conditions. In these experiments, 36 healthy males in their 20s underwent a year-long study of nutritional manipulation. The initial 3 month stabilization period ensured that the participants met their nutritional needs; the 6 month period that followed was marked as the derivation period, such that the men consumed only 55% of their estimated energy needs during this time. A 12-week re-feeding period followed, in which the participants were provided with adequate energy for nutritional rehabilitation (206).

The men in that study lost an average of 24% of their initial body weight, with a reduction in RMR of 39%; after accounting for changes in body weight and body composition, the reduction not attributed to loss of fat free mass was estimated to be about a 35% reduction in RMR (207).

Metabolic Adaptation: Review Articles

In 2006, Stiegler and Cunliffe performed a comprehensive review of the science exploring the role of diet and physical activity in maintaining fat-free mass and RMR during weight loss (208). While this review is 12 years old, it is a comprehensive evaluation examining evidence from dietary intervention studies, exercise intervention studies, and a combination of both. A review of ten diet intervention studies included various dietary interventions in which the effects on RMR and body composition of variable carbohydrate, low glycemic load, and variable fat and protein content diets were explored within weight loss interventions. It was found that low fat diets did lead to weight loss, but the loss was often accompanied by reductions in fat free mass (208). This review also demonstrated that although some evidence was seen with the benefit of higher protein diets in the preservation of lean body mass and a reduced loss of RMR, adequate evidence to determine this effect is lacking (208).

That same review considered the effect of exercise on RMR. In these studies, the effects of various types of physical activity on RMR, in the absence of dietary intervention, were explored. A review of ten studies showed that the effect on body composition depended largely on the type of exercise investigated. For example, concerning aerobic exercise, a small decrease in total body weight and in fat mass was seen in studies that prescribed prolonged, submaximal bouts of regular exercise (208). In exploring a study that incorporated resistance exercise and both resistance and aerobic (combination) exercise over a 20-week intervention, a small but significant within-group increase in RMR occurred in the resistance-trained participants (1451 ± 62 vs. 1495 ± 63 kcalories per day), but a significant within-group decrease in RMR was seen in the combination exercise group (1336 ± 42 kcalories per day post-treatment, vs. 1389 ± 39) (209). Other studies reviewed in these categories showed no significant changes in RMR, in spite of increases in LBM in cases of adequate amounts of exercise, suggesting that even in the presence of LBM increase, RMR failed to subsequently increase (208).

In reviewing 16 studies that incorporated both dietary and exercise interventions, it was found that although the conservation of lean mass was seen in some studies in which aerobic exercise was added to dietary interventions promoting weight loss, RMR changes did not mimic these alterations (208). When compared to the addition of aerobic exercise to caloric restriction, the addition of strength training exercise to caloric restriction was more likely to be associated with the conservation of LBM and RMR (208). When investigating studies that incorporated both forms of exercise into calorie-restricted interventions, the complex nature of considering the decreasing effects of caloric restriction, as well as the potential benefits of diets higher in protein, along with the mixed results of physical activity on RMR make it difficult to come to conclusive findings. However, the evidence suggests that the typical reduction in RMR from dietary interventions can be somewhat mediated by the addition of resistance exercise (208).

However, this review also sheds light on the need for more conclusive evidence relating to all aspects of RMR changes resulting from both dietary and exercise interventions.

In 2007 Major and colleagues conducted a review of the literature to determine the clinical significance of metabolic adaptation (90). The authors reviewed metabolic adaptation as the presence of a reduction in energy expenditure that is greater than predicted, based on changes in fat and fat-free mass, in the presence of a negative energy balance, and focus on the potentially significant effect this condition has on the ability of those in need of weight reduction to achieve and maintain success (90). This review discusses three conditions that may be associated with the effect of metabolic adaptation on individuals who may be more disposed to its effect: body weight loss and regain cycling, organochlorine plasma concentration, and hypoxia in the presence of severe obstructive sleep apnea (90). The first condition, body weight loss and regain cycling, has been associated with decreased RMR beyond what might be expected from weight loss (210). The second condition, defined as chemical products that accumulate in the fat of organisms due to their lipophilic properties) (90), has been positively associated with BMI and fat mass (211), and the presence of plasma organochlorines in those who have lost weight, has been associated with decreased measures of RMR (90). Severe obstructive sleep apnea, which is common in individuals with overweight or obesity (212), has been associated with reduced RMR; as the severity of the condition increased, RMR decreased (213). This review goes beyond acknowledging the presence of metabolic adaptation; it identifies potential factors that may affect the susceptibility of some to experience its effects, and the clinical implications of this condition which include difficulty in achieving weight loss and maintenance success (90).

More recently, Tremblay and colleagues further extended the concept of metabolic adaptation's clinical significance by examining the condition's potential role in fat loss resistance, as well as in reduced satiety of individuals experiencing metabolic adaptation and the long-term continuance of the condition after weight reduction (87). This review suggests that the effects of metabolic adaptation following weight reduction include a significant decrease in RMR, beyond what is anticipated through body composition change. The review further demonstrates that the inter-individual variability of this energy expenditure reduction predisposes some individuals to experience a larger effect from metabolic adaptation, and this in fact leads to a resistance of further reduction in body fat (87). Additionally, the energy-reduced state accompanying weight reduction has been associated with changes in hunger and satiety hormone levels, such that there is a decrease in leptin, peptide tyrosine tyrosine (PYY) and glucagon-like peptide 1 (GLP-1) and an increase in ghrelin; this state drives the desire to eat, and can make it that much more difficult to maintain weight reduction (87). Moreover, the extent to which individuals experience metabolic adaptation has been positively associated with increases in appetite, again supporting the concept of some individuals being more greatly affected by this condition (87).

This review also demonstrated that short-term weight loss interventions (defined as < 6 weeks) yielded energy expenditure reductions that were twice as high as those from longer-term interventions (87); this is important to the current dissertation projects because the main weight loss study was an eight-week intervention. In summary, this paper highlights the co-existence of reduced energy expenditure coupled with the increase in the drive to eat as having meaningful, clinical significance in the cause of reduced weight maintenance success, and that some individuals are more susceptible to these effects.

Muller and Bosy-Westphal conducted a review in which the many factors that affect metabolic adaptation were identified and discussed (214). These included but were not limited to a reduction in sympathetic nervous system activity, as well as decreased leptin and thyroid hormones (214). This review demonstrates that during underfeeding, adequate, consistent kinetic measurements have not been able to show correlations between hormonal changes and the possible effects of metabolic adaptation (214). However, both clinical data and mathematical modeling of weight loss, from body composition and RMR data of healthy weight and overweight/obese participants, further support the existence of metabolic adaptation (214). Furthermore, the review establishes that if the expected change in RMR can be determined using a mathematical model that incorporates change in both weight and in body composition, the definition of metabolic adaptation can be defined as the greater than expected change in RMR with underfeeding (214).

In 2016, a paper published by ten Haaf and colleagues established additional support for the reduction in energy expenditure in the presence of weight loss, above and beyond that which would be expected from changes in body fat and fat free mass in a group of overweight and obese adults (92). The research group combined data from nine studies in which weight loss interventions including a low calorie diet as part of the protocol were present, in an effort to explore differences in the presence of metabolic adaptation between younger and older groups of participants. In all studies, RMR was measured using a ventilated hood indirect calorimetry system. Two hundred fifty-four participants were included in the analyses, and all participants had a BMI >25 kg/m^2. Metabolic adaptation was defined as the difference between post-weight loss predicted RMR and post-weight loss measured energy expenditure. Researchers used the median age of 55 years as the cut off, and participants over this median age were considered older participants vs. those under 55 as the younger participants. Paired samples t tests were used to identify differences within each age groups, and independent samples t tests were used to detect differences between these two groups. A linear regression analysis was used to identify predictors of RMR including fat mass, fat free mass, age, gender. Results showed that for all participants, there was a significant reduction in measured RMR post weight loss interventions (1729±326 kcalories/day) compared with predicted RMR (1771±238 kcalories/day); this signified a metabolic adaptation of 42±171 kcalories/day (95%CI 21,63) (92).

In considering group differences between older and younger participants, there was a significant metabolic adaptation in the older group (64±185 kcalories/day, 95% CI 32,96); however, there was no significance in the younger group (19±152 kcalories/day, 95% CI –9, 46). In further analyses, when correcting for pre-weight loss measurements and predictive calculations, metabolic adaptation was also significant for the older group (57±196 kcalories/day 95% CI 23,91), but remained non-significant for the younger group (26±165 kcalories/day, 95%CI -4,56). Additionally, the linear regression model demonstrated that the magnitude of the metabolic adaptation was significantly higher in the older group than in the younger group (p=.048) (92).

That study was important because it pulled from nine other weight loss studies that examined the presence of metabolic adaptation, and created a sample size large enough to determine differences based on age as well as creating a linear regression model to look at predictors of metabolic adaptation. The results showed that metabolic adaptation may exist primarily in older adults, and may be related to age; additionally, that study supported that fat free mass, fat mass and age explained 70% of the variation in RMR at baseline. Further, these findings add new information to what is known about metabolic adaptation as it relates to age, due to the presence of metabolic adaptation in older adults but not in younger adults, in spite of both groups maintaining the same level of fat free mass.

Strengths of that study include the large sample size, and the consistency of measurement tools (air displacement plethysmography for body composition and indirect calorimetry for RMR measurement and means of weight loss (hypocaloric diet). Limitations include that there was no information given on the demographics of the participants, so it is difficult to know if the results are generalizable to larger populations; also, no information was provided on the physical activity monitoring of the participants from each of the nine studies. However, in spite of these limitations, the study shed new light on possible differences in the presence of metabolic adaptation in different age groups.

Metabolic Adaptation: Experimental Studies

One of the most frequently cited studies in the metabolic adaptation literature was published in 1995 by Rudolph Leibel and colleagues (88). In this landmark study, the effects of body weight change on energy expenditure of both 18 obese and 23 non-obese participants. Participants were initially provided with adequate nutrition through liquid meals to achieve weight maintenance over a 10 day period, during which body composition was analyzed using hydrodensitrometry, and energy expenditure was measured by indirect calorimetry (88). After the initial weight maintenance phase, participants were provided with foods to consume to ingest between 5,000 – 8,000 kcalories per day, in order to achieve a 10-20% increase in body weight from their initial weight. This process required a 4-6 week period for the non-obese participants to achieve the goal weight, and a 6-10 week period for the obese participants to reach this increased weight, and after a 14-day stabilization period at the new weight, body composition and energy expenditure measurements were taken again. Participants were then placed back on a liquid diet, providing 800 kcalories per day, to reach each participant's initial body weight (88). After a 14 day period of stabilization, the measurement studies were performed again. Finally, 9 of the obese participants and 11 of the non-obese participants underwent further weight manipulation by consuming 800 kcalories per day from the liquid diet over a 4 to 7 week period (nonobese participants) and 6 to 14 weeks (obese participants), until a 10 percent loss from the initial body weight was achieved. After a stabilization period of about 14 days, the measurement studies were repeated, and following this, ten of the obese participants were given the 800-kcalorie liquid formula to achieve an additional 10% weight reduction from initial weight (totaling 20% weight loss from initial body weight).

Results from that study showed that after controlling for body composition, total energy expenditure increased by 16% and decreased by 15% after a 10% increase or decrease in body weight, respectively (88). This is significant because the changes identified in energy expenditure seem to promote the return to the original weight, regardless of the direction of the weight change; when participants gained weight, there was an increase in energy expenditure, and when they lost weight, there was a reduction in energy expenditure. Results also showed that for obese participants, both total and RMR (expressed as kcalories per kilogram of fat free mass) were significantly higher when compared to nonobese participants (47±7 vs. 51±7 kcals/kg, p=.016, and 28±5 vs. 35±7 kcals/kg, *p*<.001, for total and RMR levels at initial weight measurements, respectively), and the effects of weight loss on these values demonstrated that total and RMRs were significantly lower after weight loss of 10% and 20% when compared to the energy expenditures taken at the initial weights of the participants 39±3 kcals/kg and 42±5 kcals/kg for nonobese and obese participants after a 10% weight loss (88). There was no significant further decline in energy expenditures at 20% when compared to the 10% weight reduction measurements for obese participants who lost 20% initial weight (39±4 kcals/kg for obese participants who lost 20% initial weight, vs. 42±5 kcals/kg fat free mass for 10% loss in obese participants) (88).

That study is important because it was the first to demonstrate the marked change in energy expenditure remains in place after the dynamic weight fluctuations are stabilized for short periods of time (in this case, about 10-14 days). Additionally, the results demonstrate that a leveling off of the drop in energy expenditure after a certain weight loss point has been reached, because when participants who lost 10% of their initial body weight went on to lose another 10% of their weight, there was no significant additional reduction in energy expenditure. That study supports the existence of metabolic adaptation, as a condition that seems to promote the return to the original weight.

In another experimental study, Doucet and colleagues sought to explore metabolic adaptation in an effort to confirm its existence as well as to give objective measurements of the decrease in RMR and to identify predictors of the decrease in RMR in obese participants exposed to a weight loss program (89). Participants were 15 obese men and 20 obese women who were given either a weight loss drug (fenfluramine, which was shortly after taken off the market due to cardiovascular side effects) or a placebo along with an energy restriction using diabetic exchange lists (89). Participants came into the lab at baseline, and after 2 and 8 weeks during the weight loss program, in addition to 2-4 weeks after the end of the 15-week program (89). Body composition was measured using hydrodensitrometry, and RMR was measured using indirect calorimetry. Multiple regression analyses were used to predict RMR at baseline, 2 and 8 weeks into the program, and 2-4 weeks after the program ended, and changes in RMR were calculated; metabolic adaptation was determined to be the difference between the changes in predicted RMR from the equations and deviations in measured RMR (89). No significant differences due to the weight loss drug were observed between groups. In the exploration of predictors of RMR, results from that study showed that fat free mass was the greatest predictor of RMR in men (r=.62, p <.0001) as well as women (r=.63, p<.001); in both cases, adding fat mass to the model increased the variance that body composition attributed to RMR to .67 and .68, respectively (89).

Results from that study also showed significant decreases throughout the weight loss program in both measured and predicted RMR in men, but the differences did not reach significance in women (89). Furthermore, the researchers followed the predicted and measured RMR values from baseline to 2-4 weeks after the end of the intervention. In men, the initial predicted RMR and measured RMR were similar, but at the eighth week, the predicted value was significantly greater than the measured value (p<.05). There were no statistically differences between predicted and measured RMR at the end of the program in men. In women, however, the initial baseline measured RMR was greater than the predicted value, but at both the 2- and 8-week marks, these values were similar to the predicted values. After the end of the program, the predicted values were significantly lower than the measured RMR values in these women (p<.01) (89). In exploring the predictors of the differences between predicted and measured RMR values, the researchers determined that those participants who had higher RMR and lower fat free mass at baseline were more likely to produce decreased measured RMR values compared to their predicted RMR values; these were particularly strong predictors for women (89).

That study lent new insight into the metabolic adaptation literature because it offered sequential measurements throughout a weight loss intervention from baseline until up to 4 weeks after the end of the program, taking body composition and RMR measurements at baseline, 2, 8 and 17-19 weeks of the 15 week program. This was critical because while the literature to that point had demonstrated the effect of body composition changes on RMR and identified a gap between predicted RMR based on body composition and actual measured RMR in the presence of weight loss, that study was the first to demonstrate that once participants returned to eating adequate energy to prevent further weight loss, and energy balance was restored, the metabolic adaptive component decreased. That study also identified that differences in metabolic adaptation may exist between men and women, including the reinstitution of energy expenditure after the reestablishment of energy balance, which appeared to be more strongly identified in women (89). Furthermore, while the literature had previously suggested that certain individuals are more prone to the effects of metabolic adaptation after weight loss in the presence of a negative energy balance, that study identified presence of higher RMR and lower fat free mass as specific predictors of developing reduced RMR with weight reduction. This is important due to the clinical implication of identifying those who may have increased difficulty in maintaining weight reduction due to the presence of metabolic adaptation. Finally, it reinforces the concept that metabolic adaptation seems to be attributed to a negative energy balance as opposed to simply a result of weight change.

Wang and colleagues added to this body of literature in 2008 in a significant way when they explored associations of the effects of metabolic adaptation of physical activity energy expenditure (PAEE) and RMR during weight loss with future weight regain (113). That study examined 34 women who were overweight or obese and followed them over a 20-week low calorie weight loss intervention; participants were randomly assigned to either a low calorie diet only group, a diet plus low intensity exercise group, or a diet plus high intensity exercise group. Participants provided a four-day dietary recall upon beginning the study, and RMR was measured with indirect calorimetry before and after the 20-week intervention; participants also self-reported physical activity and wore a triaxial accelerometer during the first and last weeks of the intervention. Participants returned after the intervention ended for data collection and returned at 6 months and 12 months as well.

Results of the study showed that there were similar decreases in body weight, lean body mass, and fat mass across all groups. Although there were reductions in RMR in all groups (% change, -10.5±10.6 for diet group; -4.7±9.6 in diet plus low intensity exercise group; -5.7± 8.7 in diet plus high intensity group, with -6.9±9.7 overall), there were no significant between-group differences in reductions of both RMR and physical activity energy expenditure (*p*<.0001 for both RMR and PAEE; p>.05 for all time by group interactions). That study also found that the women who had the greatest reductions in PAEE during the intervention were more likely to regain weight in the months following the completion of the intervention. Although not statistically significant, there appeared to be less of a reduction in RMR in the groups who were randomized into exercise groups when compared to the diet only group. This is significant to the current dissertation body of research because one of the three metrics of the weight loss intervention is increasing the number of steps taken by the participants; the findings of the Wang et al. study suggest that those who declined in physical activity over the course of the intervention may be at a higher risk of regaining any weight lost during the intervention (113).

Pointing out some of the limitations in previous research, including lack of weight-matched controls, the absence of weight stability during testing, or a too-brief period of weight instability prior to testing, Rosenbaum and colleagues sought to improve upon previous study design and add to the body of research relating to metabolic adaptation by examining the long-term persistence of this condition in participants who lost a significant amount of weight (≥10%) for an extended period of time (≥1 year) (102). This research recruited 7 participants who had lost ≥10% initial weight and had maintained this loss for ≥1 year, and who had participated in previous research studies by the group. The researchers matched these participants with two gender/weight control participants – one who was maintaining a usual body weight, and one who had achieved recent successful weight loss, forming seven trios of gender and weight-matched participants. This was done to examine the existence of a long-term reduction in energy expenditure that was above what would be expected due to changes in body weight or body composition. Body composition was measured by hydrodensitrometry, and RMR was measured by indirect calorimetry after weight stabilization was achieved in all weight-matched trios.

Results of that study showed that the residual differences between actual or measured total energy expenditure (TEE), RMR and non-resting metabolic rate (NRMR) and the values predicted based on regression equations that take into consideration age and body composition when accounting for energy expenditure were less than zero, suggesting that there are in fact significantly lower energy expenditure in the participants who lost weight recently and who have sustained a weight loss, when compared to the participants who were stable at an initial weight (for weight loss-sustained participants = -422±104 residual kcalories per day, $p<.01$ compared to zero and compared to participants with stable initial weight; for weight loss-recent participants, -460±56 kcalories per day, $p<.01$ compared to zero and compared to participants with stable initial weight) (102). Moreover, there were no significant differences in residual differences between participants who had lost weight recently vs. those who had maintained the loss for > 1 year; therefore, these results support the concept that metabolic adaptation is persistent over time (102).

One limitation of that study is the low number of participants who had successfully maintained a significant weight loss for at least one year. However, strengths include of the study include that these participants were gender and weight-matched with participants who were stable at usual weight and who had lost weight recently; another strength is that all participants achieved weight stability prior to testing in that study. These results are important to this body of research, because they show that metabolic adaptation exists in weight-reduced participants both immediately after weight stabilization, and persists over the longer-term weight stabilization period of time after weight reduction.

Two of the more interesting studies published in the following years relating to metabolic adaptation were completed during and after a nationally televised weight reduction program. The first, published in 2012, explored the existence of metabolic adaptation right after the weight reduction contest (99), and the other, published in 2016, explored this condition six years after the weight reduction contest (91). The first study examined body composition, RMR, and total energy expenditure throughout the intervention at three time points: at baseline, week 6, and week 30. Sixteen participants (7 males, 9 females) between the ages of 20-56 years (mean 33±10 years) completed baseline and week 30 measurements; 11 completed the week 6 measurements due to the nature of the competition design. Participants underwent 90 minutes per day of supervised hard physical activity, and were encouraged to participate in up to three additional hours of unsupervised exercise. They were not placed on a kcaloric restriction but were encouraged to consume a diet providing a minimum of 70% of their baseline energy requirements. Body composition was measured by dual-energy x-ray absorptiometry, RMR by indirect calorimetry, and TEE by doubly labeled water at baseline.

Results of that study showed that large amounts of weight were lost, with nearly 40% of their initial weight lost at the week 30 measurements; most of the loss was attributed to fat mass, at nearly 83%, with 17% of the loss coming from fat free mass (99). In spite of these favorable proportions weight loss, however, measured RMR at week 6 and week 30 decreased from baseline measurements by 356±399 kcals/day and 789±483 kcalories per day, respectively (99). Upon calculating expected declines in RMR due to body weight and body composition changes at week 6, RMR still dropped by 244±231 kcalories per day more than expected. At week 30, the drop was 504±171 kcalories per day more than was anticipated based on the body weight and body composition changes. The degree of metabolic adaptation measured in kcalories per day was significantly, positively correlated with the amount of weight lost (r=.61, p=.01). Additionally, RQ at baseline was calculated to be .76±.05, and remained relatively consistent at week 6 (.76±.04) and at week 30 (.75±.03) with no significant differences in this measurement (each with p>.05); this suggests that participants continue to utilize fat as substrate fuel at rest (99). Finally, TEE increased from baseline to week 6 (from 3727 to 4531 kcalories per day, $p<.03$), in spite of the reduction in RMR, indicating a significant increase in physical activity; at week 30, TEE levels were similar to baseline, which can be attributed to continued aggressive physical activity given the substantial decline in fat free mass (99).

Strengths of that study include the very controlled conditions of the participants throughout the weight loss competition. Additionally, the measurements of body composition by dual energy x ray absorptiometry and TEE by doubly labeled water, as well as indirect calorimetry for measuring RMR, are strengths of that study. A limitation of that study is that the measurements of energy expenditure took place during continued active weight reduction, as opposed to the suggested weight stability for this measurement. However, the previously discussed study by Rosenbaum and colleagues supports that at least some of the reduction in RMR can be attributed to metabolic adaptation even in the presence of fluctuating levels of energy deficit (99, 102). The results of that study contribute important information to the metabolic adaptation literature. First, that study demonstrates that even in the presence of large amounts of physical activity, and subsequent increases in TEE, there still exists a significant reduction in RMR in spite of low losses of fat free mass. This reduction in RMR increased as the weeks went on, and after the evening out of TEE, the reduction in RMR remained significant. This supports the concept that metabolic adaptation is persistent over time, even after 30 weeks of weight reduction in the presence of relatively preserved fat free mass and continued robust exercise. Finally, the scope of the metabolic adaptation was moderately, positively correlated with the amount of weight lost, which also lends support to the adaptive nature of the adaptation; the greater the weight loss, the greater the reduction in RMR.

Fothergill and colleagues added to this finding by recruiting 14 out of the 16 original participants from the previous study and weight reduction competition, and completed body composition and REE measurements 6 years after the end of the competition (91). Participants' body weights were monitored remotely via Bluetooth technology two weeks prior to admission to the National Institutes of Health Clinical Center for a 3-day stay for data collection and monitoring. During this inpatient stay, body composition was measured using dual x-ray absorptiometry, and RMR was measured using indirect calorimetry. A least squares best-fit linear regression equation for RMR was used to predict expected energy expenditure based on by age, gender, fat mass, and fat free mass. Metabolic adaptation was defined as the difference between the predicted energy expenditure and actual measured energy expenditure by indirect calorimetry. Results showed that there was significant weight regain after 6 years. The participants collectively lost 58.3±24.9 kg at the end of the weight reduction competition. After 6 years, the mean weight loss was reduced to a mean of 17.3 kg (11.9±16.8%) with wide between-individual variability; additionally, most of the weight change (80%) at both time points (week 30 of the competition and after 6 years) resulted from changes in fat mass (91). Results showed that there had been significant reductions in RMR from baseline to week 30 of the competition (2607±649 vs. 1996±358 kcalories per day, respectively, p=.0004); the measurements from the 6-year mark were similar to those of the week 30 measurements (1903±466 kcalories/day, p=.35). Even more notably, from baseline measurements, the metabolic adaptation increased over time, from -275±207 kcalories per day (p=.00025) at 30 weeks to -499±207 kcalories per day after 6 years ($p<.0001$). These results are significant because they demonstrate that the decline in RMR that takes place above and beyond what is expected from changes in body weight and body composition are persistent, and remain over the long term, even up to 6 years; furthermore, this adaptation takes place even in the presence of a two week weight stabilization period (91).

Strengths of that study include that they were powered to detect a metabolic adaptation of at least 220 kcals/day, using 12 participants. The power analysis was such because the researchers did not anticipate recruiting all 16 of the original participants; however, they were successful in recruiting 14 of these participants to come back for the analyses. Strengths also include the long-term nature of the follow-up of metabolic adaptation measurements. Limitations include that the researchers had to use a different metabolic cart to measure REE at the 6 year mark; however, the potential metabolic cart bias was assessed and found that the newly used cart had no significant energy expenditure bias compared to the original cart used at baseline and at the 30 week mark (91).

In 2013, Bosy-Westphal and colleagues examined the effects of weight loss and regain on body composition and RMR changes in 103 young overweight and obese adults by (215). Participants participated in a 13 week weight loss intervention in which they received nutrition counseling and their kcaloric intake was restricted to 800-1000 kcalories per day, half of which consisted of kcalories from two ingested shakes (BCM-Diät, PreCon, Darmstadt Germany), which provided the Recommended Dietary Allowance (RDA) (215). A subsample of 47 participants were selected based on their status of having either regained ≥ 30% of weight lost, or maintaining a stable weight after loss. Body composition was analyzed using air displacement plethysmography, and RMR was measured using indirect calorimetry. All measurements were taken at baseline, at the end of the weight loss intervention, and at a follow-up, which took place 6 months after the end of the intervention.

Results showed that RMR, after adjustment for body composition, in participants who were deemed weight stable was statistically unchanged during weight loss and subsequent follow-up (-0.14±1.22 and -0.19±.88, p>.05). In the group who regained ≥ 30% of weight lost, RMR taken at the end of the weight loss intervention was significantly decreased in comparison to baseline measurements (-0.39±0.57 and -0.04±0.69, p<0.01) (215). Additionally, calculations were performed to assess what the RMR should have been given the weight regain, and it was determined that RMR should have had a complete recovery; that is, the RMR should have returned to where it was prior to the initiation of the weight loss intervention. However, RMR remained below the baseline value at the 6-month follow-up mark (-0.39±0.57, p<.01). Furthermore, there was not a significant difference in RMR normalized for body composition (calculated as measured RMR – calculated RMR) between the stable weight participants and those who had regained weight between baseline and end of the intervention (-0.14±1.22 vs. -0.39±0.57, respectively, p=0.132), or between end of the intervention and the 6-month follow-up (-0.19±0.88 vs. -0.04±0.69, respectively, p>0.05). These results demonstrate the presence of a metabolic adaptation in participants who regained ≥ 30% of the weight previously lost, but this adaptation was not significantly present in those who lost the weight and remained stable at the new, lower weight. A strength of that study is the relatively large sample size for a weight intervention study, as the researchers were able to recruit 47 participants from a larger sample of 100; this allowed them to select individuals based on their weight stability versus weight regain for comparison (215). One limitation of that study, however, is that the sample was primarily Caucasian, which limits generalizability to other populations. Another limitation of that study is the lack of inclusion of physical activity. Therefore, it is difficult to assess to what degree the levels of physical activity may have impacted RMR, particularly in the group of participants who were able to maintain their weight loss.

Another study published in 2013 explored the effects of weight loss and weight maintenance on metabolic adaptation (216). That study was similar to the previously discussed study, as it recruited 22 overweight/obese men and 69 overweight women and took them through an 8-week weight loss intervention, which consisted of following a very low density diet (VLED), followed by a 44-week maintenance period. Body composition was measured using a three-compartment model based on body weight, body volume and total body water; body volume was measured using air displacement plethysmography. RMR (RMR_m) was measured using an open-circuit ventilated-hood system, and predicted metabolic rate (RMR_p) was calculated using fat mass and fat free mass to account for body composition changes. Metabolic adaptation was defined as the difference between RMR_m divided by RMR_p.

That study found that there was a significant decrease from baseline in measured RMR from 7.31±1.04 MJ/day to 6.64±.88 MJ/day after following the VLED for 8 weeks ($p<.001$) (216). Resting metabolic rate was measured after 20 weeks and after 52 weeks (6.92±1.05 MJ/day and 6.97±1.00 MJ/day, respectively; $p<.001$ for both compared to baseline values). Similar decreased were seen in predicted calculations of RMR given the decrease in body weight of the participants; at baseline, RMR_p = 7.29±1.03 MJ/day, and decreased to 6.91±0.97 and 7.04±1.04 MJ/day at 8 and 52 weeks, respectively (both $p<.001$ compared to baseline values). In terms of the ratios of RMR_m to RMR_p to assess the degree of metabolic adaptation in these participants, there was a significant decrease from baseline values at 1.004±.077 to .963±.073 MJ/day at 8 weeks, $p<.01$. After 20 and 52 weeks, the ratios continued to reach statistical significance in their reductions (.983±.063 and .984±.068 MJ/day, respectively, both $p<.05$); however, after controlling for percentage of weight loss, no significant differences were found ($p=.206$) after 8, 20 and 52 weeks. Of note, positive, moderate correlations were found between these ratios and percentage of weight loss (after 8 weeks: R^2 = .47, p<.05; after 20 weeks: R^2 = .52, $p<.05$; and after 52 weeks, R^2 = .60, $p<.05$). These associations are important because they suggest that participants who lost more weight had a more pronounced reduction in RMR, and these reductions were similar across the 8-, 20- and 52-week time points (216). That study is also important because it demonstrated the presence of metabolic adaptation after weight reduction, and that this condition persisted up to a year after the weight loss (216).

A strength of that study is that the study period spanned one year's time, which allowed for a long period of weight maintenance. A limitation of that study is that dietary and physical activity data were not standardized throughout the 44-week follow-up period. However, the existence of this limitation may lend more credence to the persistence of metabolic adaptation in the long term under uncontrolled conditions, which may be more reflective of real-world weight reduction and maintenance scenarios.

Jaime and colleagues in 2015 examined the effect of a short-term energy restriction on energy expenditure, more than what would be predicted based on changes in body composition, in a group of adult overweight and obese women (217). This research group took this question a step further by considering the compliance of the women enrolled in the study and how compliance may have affected energy expenditure. Twenty-two women between the ages of 22-44 years (BMI range of 25-32 kg/m^2 were recruited and placed on a high protein, calorie-restricted diet that provided 20 kcalories/kg body weight for three months. Body composition and RMR were assed using a Lunar Encore double beam densitrometer (DEXA) and an indirect calorimeter, respectively, at baseline and at three months (217). An accelerometer was used to assess physical activity energy expenditure, which the participants wore three days per week during the weight loss intervention (217).

Results of the body composition analyses showed that weight decreased significantly by 5.3±4.3% (p <.05) in comparing baseline to the end of the three-month intervention, and fat mass also went down by 2.3±1.9% (p <.05). On the other hand, FFM remained relatively preserved (change from baseline to 3 months = +2.5±1.9%). Results also showed that when compared to baseline, there was a significant reduction in RMR (-

5.6%, $p < .05$) and in RMR per kg body weight (-6.2%, $p < .05$). Fifty-four percent of the participants who participated in the weight loss intervention were considered to be compliant with the treatment, as defined by weight loss of ≥ 5% (217). When considering the results according to compliance, there were significant reductions in RMR and RMR/kg FFM only in the compliant group (-164±168 kcalories/day and -4.3 ±4.6 kcals/day per kg FFM (217). That study contributes to the literature because it showed that even in the presence of preserved FFM, there was still a decline in RMR, which demonstrates the presence of metabolic adaptation. In addition, that study showed that participants who were deemed to be compliant to the weight loss intervention, as defined by weight loss, demonstrated decreases in RMR, suggestive of metabolic adaptation in these participants.

Strengths of that study include the inclusion of physical activity monitoring by way of an accelerometer, as well as the monitoring of compliance in the study. Another strength is the weekly monitoring of the participants with a dietitian, although the use of dietary data are not present in that study. A limitation of that study is the lack of dietary data available; the paper cites the lack of precision and presence of under-reporting that is typically found in dietary data collection as the reason for no dietary data collected (217). Instead, the researchers defined compliance based on weight loss percentage, which could also be attributed to the presence of other things than compliance to the weight reduction regimen (examples could be increased physical activity on non-monitored days, support systems for healthy eating in place, and socio-economic status to name a few). Another limitation of that study is the small sample size, as well as lack of control group or maintenance phase following weight reduction, to assess the presence of metabolic adaptation over time. However, in spite of these limitations, that study contributes to the knowledge base of metabolic adaptation by showing that metabolic adaptation can take place even with preservation of fat free mass, and in compliant participants who lose at least 5% of their initial body weight.

In summary, many review articles and experimental studies provide evidence for the existence of metabolic adaptation, in the presence of weight reduction, a negative energy balance, and after weight stability has been achieved. The literature has demonstrated that this adaptation takes place even in the presence of the preservation of fat free mass, and is persistent over long periods of time, even up to six years after weight reduction. The existence of metabolic adaptation is an important issue to consider in the treatment of obesity, because by its very nature, it works to preserve human life in that the body decreases how much energy it expends in the scenario of weight loss and inadequate energy intake. While this adaptation plays a role in human existence, in the era of obesity and the need to decrease obesity-related disease, this adaptation can be detrimental to the success of a person who is trying to achieve and maintain a healthier weight. Metabolic adaptation has been identified mainly in studies in which moderate to large weight loss has occurred; therefore exploring the effects of metabolic adaptation within an eight-week self-led weight loss intervention, in which smaller changes in weight are anticipated, may be beneficial.

Conclusion

In conclusion, obesity remains a significant public health problem (1, 134, 137), and continues to challenge researchers to explore novel ways in which this health condition can be managed. Self-monitoring of both dietary intake and physical activity is a critical component of weight loss (22, 218), and new ways to aid the self-monitoring of individuals seeking weight reduction should be explored. Eating rate, or the amount of food consumed per unit of time, has been associated with energy intake (12, 13, 35) and obesity (3, 4). The ELMM device is capable of tracking dietary intake and physical activity through monitoring of bites and steps taken, respectively (23, 25). The ELMM is also capable of tracking eating rate in free-living settings, but this aspect of the device has not yet been validated in free-living settings. Additionally, the metabolic effects of weight reduction including metabolic adaptation and changes substrate oxidation are important to consider in the context of weight loss and maintenance, because these adaptations may play a role in impeding the ability to maintain weight loss (88, 102, 216). Therefore, the purpose of the current dissertation is to explore the effects of a novel wearable device on weight loss outcomes; to validate the device's ability to measure free-living eating rate; and to explore the metabolic effects of weight change and its associations with weight maintenance within an eight week weight loss intervention.

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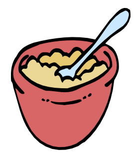
Appendix A: Organizational Table of Projects

Project	Name of Study	Recruitment of Participants	Study Design	Primary Hypothesis	Primary Outcome	Secondary Hypothesis	Secondary Outcome
One	Bite Counter Study (BCS)	21	Within participants experimental design	Primary hypothesis: The eating rate of participants measured in a lab test meal after wearing the Bite Counter for one week will be slower than the eating rate measured before the Bite Counter intervention.	Eating rate as measured by UEM	Post-laboratory meal satiety will be higher in the participants after wearing the Bite Counter for one week than before wearing the Bite Counter for one week	Appetite as measured by VAS scales
Two	Eat Less, Move More Study (ELMM)	65	Between groups experimental design	Participants in the experimental group with the ELMM within an eight week weight loss intervention will lose more weight than participants without the ELMM within an eight week weight loss intervention	Body weight	Eating rate, free-living energy intake, and body fat percentage will decrease; estimated physical activity will increase	Eating rate, free-living energy intake, body composition, and estimated physical activity
Three	Physiological and Behavioral Add-On Study (PABA)	20	Between groups experimental design	Participants in the experimental group with the ELMM within an eight week weight loss intervention will have a lower reduction in metabolic rate than participants without the ELMM within an eight week weight loss intervention	RMR as measured by indirect calorimetry	Participants in the experimental group with the ELMM within an eight week weight loss intervention will utilize more fat for energy than participants without the ELMM within an eight week weight loss intervention	Substrate utilization (source of energy for metabolic processes)

Appendix B: **Project 3 Advertising Flier**

****<u>URI RESEARCH STUDY</u>****

<u>Would You Like To:</u>



- *Earn **$200***
- *Enjoy 2 FREE breakfasts*
- *Have your body composition, RMR, and fitness level measured*
- *Learn eating techniques to help with weight management*
  - *Receive free diet and weight management education and materials*

If you…

- are a non-smoker
- are between 18-60 years old
- have a BMI between 27-37 kg/m^2

…you may qualify for a nutrition research study conducted by the URI Nutrition & Food Sciences Department.

<u>The study involves</u>:

- *1st lab visit of ~45 minutes*

- *2nd and 4th lab visits of ~2 hours each (includes free breakfasts)*
- *3rd and 5th lab visits of ~ 1 ½ hours each*

Principal Investigator: Dr. Kathleen Melanson

Energy Balance Lab, University of Rhode Island

If you are interested, contact the URI Energy Balance Lab

Email: elmmstudy@gmail.com or call 874-2067

or call 874-2067

elmmstudy@gmail.com

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Appendix C: **Instructions for Bod Pod Testing**

In order to have the best possible results, follow these simple instructions:

- No food, drink or exercise at least 3 hours prior to testing.
- Use the restroom before testing, if necessary.
- Don't apply any lotions or skin creams prior to your test.
- Remove glasses and jewelry (if possible).
- Wear minimal, form-fitting clothing.
- Men: Thin fabric shorts, lycra/spandex-type swimsuit or single-layer compression bike-style shorts (no padding
- Women: Lycra/spandex-type swimsuit or bike-style shorts and sports bra (no wire or padding)
- Because of the sensitivity of the equipment, schedule subsequent visits under the same conditions (time of day, hydration levels, amount of facial and body hair, same day of cycle (women), etc.).
- A swim cap will be provided to compress any air pockets within the hair.

Appendix D: **Universal Eating Monitor (UEM) Protocol**

1. Turn ON computer and wait for desktop to display before proceeding

Ensure balance is level; if not, adjust leveling feet at rear to center the air bubble

2. Turn ON balance by pressing **ON** and wait for gram display before proceeding

3. Internally calibrate the balance by pressing **Cal/Menu** until **Cal int** is displayed

   Wait until **Cal done** is displayed before proceeding

4. Zero the balance by pressing **O/T**

5. Open an Excel Spreadsheet

   (a) Either double click on the Excel icon on the desktop or select the Excel application via the All Programs menu found by clicking on the Start button

   (b) Label it with the date (Column D) and volunteer ID# (Column E)

   (c) Size/move this spreadsheet to fit on the right side of the screen

6. Open the BalanceLink software

   (a) Double click on the BalanceLink icon on the desktop

   (b) Size/move the BalanceLink window to fit on the left side of the screen

7. Place computer cursor in Excel (Column A, Cell 1) where data will be displayed

8. To start recording, press **F11**

   (a) Time (H:M:S AM/PM) will be displayed in Column A

   (b) Weight (in grams) will be displayed in Column B

   Tip: *minimize movement of the mouse to avoid accidentally clicking on a cell and causing data to be displayed in another location on the same*

Excel spreadsheet

9. Place food (plate of pasta) on balance when ready

10. To stop recording, press **F11**

11. Save the Excel file

    (a) Choose Save As

    (b) Name the file [e.g. ELMM_Week0_ID_Date]

    (c) Select Compatibility Mode—Excel 97-2003

12. Clean up the Excel document and save changes (see next page)

13. Print the Excel document; turn on the printer and let it warm up before use

14. Close the BalanceLink software and close Excel

15. If no longer needed: turn OFF computer; turn OFF balance by pressing **OFF**

Appendix E: **Appetite Profile Visual Analog Scale**

Energy Balance Lab Satiety Rating Scale

Participant #/ ID	Condition ID	Visit #	Date

Clock Time: ________ (meal completion)

1. How hungry are you right now?

Not at all **Extremely**

2. How satisfied (satiated) are you right now?

Not at all **Extremely**

3. How much could you eat right now?

Nothing **Vast Quantities**

4. How thirsty are you right now?

Not at all **Extremely**

Appendix F: **Cholestech Standard Operating Procedures**

Cholestech® LDX System Standard Operating Procedures for the Nutrition and Food Science Department

Description

The purpose is to obtain fasting blood lipid and glucose values for research purposes. The results include total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triacylglycerol and glucose. The values are collected using the Alere Cholestech® LDX System after a fast of at least 12 hours (water is encouraged).

Required Materials and Setup

Table 1 Required Materials for Cholestech

Required Materials (All in Blood Draw Room)
4x Cholestech Machine w/ Power Cord
4x Cholestech Printer w/ Power Cord and Cable
3x Blood Pressure Machine w/ Cuff and Power Cord
Cholestech Cartridges (1 per student + 10)**
Optics Check Cassette
Lancets
Capillary Tubes and Plungers
Alcohol Wipes
Gauze Pads
Band Aids
Nitrile Gloves
Biohazard Bags w/ Stands
Sharps Containers
Hand Sanitizer
Table Covers
Results Forms (see Appendix A)
Juice Boxes
Nutrigrain Bars

** Cholestech cartridges must be kept refrigerated until the box is opened. Once a box is opened they can be kept at room temperature for 3 months.

Ordering

To request a quote on Cholestech supplies email the Fisher rep Mark Silva (mark.silva@thermofisher.com) with the item name, catalogue number and quantity. Once the quote is received forward it to Val Jenkins (val@uri.edu) indicating the items on the quote that need to be ordered.

Setup

- Each station needs a table cover, Cholestech machine, a printer, cartridges and a white multi-compartment receptacle containing alcohol wipes, lancets, capillary tubes and plungers, gauze pads, and Band-Aids.
- Each station needs two chairs. The machine operator's chair should have wheels and the students' chair should not have wheels but should have arms on both sides.
- Each table needs a sharps container, a biohazard bag on a stand, a box of nitrile gloves and hand sanitizer.

Fasting

Participants must be fasted for at least 12 hours before Cholestech testing.

Collection Protocol

1. Personal Protective Equipment (PPE) required for this procedure
    a. Nitrile gloves
    b. Closed toe shoes
2. Engineering Controls
    a. Sharps container
    b. Proper hand washing
3. Process
    a. Questions for the researcher/assistant to ask participant at sign-in:

    i. Did you have anything to eat or drink besides water in the past 12 hours?
    ii. Is there any reason why you shouldn't have a finger stick today (the flu, etc.)?

b. Questions for the Machine Operator to ask student/participant after they sit down but before the finger stick
    i. Which hand do you write with? We will do the finger stick on the other hand.
    ii. How warm are your hands? If the student's/participant's hands are cold – have them sit on them, rub them together, etc. The warmed the hands, the easier it will be to get a blood sample.

c. Finger stick procedure
    i. Position hand palm-side up with the hand below the elbow. Choose whichever finger is least calloused.
    ii. Apply intermittent pressure to the finger to help blood flow.
    iii. Clean the fingertip with alcohol. Dispose of alcohol wipe in the regular trash. Allow the area to dry.
    iv. Firmly press the lancet to puncture the fingertip. It should be on the side of the finger pad – not directly in the middle or at the top. Dispose of lancet in the Sharps container.
    v. Wipe away the first drop of blood with a sterile gauze pad. Dispose of the gauze in the regular trash.

vi. Collect blood using the capillary tube with the plunger inserted. Capillary tube should approximately parallel to the floor. Blood flows better if the hand is below the elbow.

vii. Apply a gauze pad to the puncture site until the bleeding stops. Dispose of gauze in red biohazard bag.

d. Cholestech procedure

i. Allow cassettes to come to room temperature for at least 10 minutes before opening.

ii. Make sure analyzer is plugged in and warmed up and that the printer is hooked up correctly.

iii. Remove cassette from the pouch and place on a flat surface. Only touch the short sides and do not touch the black stripe.

iv. Press RUN to turn on and test the machine. The screen should display:

1. Self test running -> Self test OK

v. The cassette drawer will open and screen will display:

1. Load cassette and press RUN

vi. Empty the sample from the capillary tube into the cartridge by depressing the plunger.

vii. Place the cassette into the open machine drawer with the black stripe on the right.

viii. Press RUN. The screen will display

1. Test Running *

ix. Dispose of all items that came into contact with blood in red biohazard bag. Dispose of lancets in the sharps bin.

x. When test is complete the results will print. Place one copy on a colored results form and one copy on a white results form. Give the **participant** the **white** results form and place the colored results from in the collection folder.

xi. Dispose of used cartridges in the sharps container.

e. Blood pressure procedure

i. Once the machine screen displays “Test Running *****” begin taking the students blood pressure.

ii. Instruct the student the sit with their back flat against the chair and both feet flat on the floor. Place the cuff above the elbow on a bare or lightly sleeved arm and secure the Velcro.

iii. Instruct the participant to rest their arm on the table and press run two times to get first value. Record the first value on the white and colored results forms.

iv. After one minute run the blood pressure test again and record the values. If the systolic and diastolic values are both within three points then remove the blood pressure cuff. If they are not within three points then wait one minute and continue running the test and recording the results until two values within three points are attained.

4. Hazard mitigation

a. If the eye is exposed to blood, wash in the nearest eye wash station for 10 minutes at 15 PSI. Lift eyelids to ensure proper rinsing.
b. If the skin is exposed to blood, vigorously scrub the affected area with soap and hot water. Remove any contaminated clothing.
c. Call 874-2121 if exposure warrants medical treatment

5. Handling and storage
    a. When not in use, Cholestech machines and supplies will be stored in the Lipid Lab in a labeled cupboard. Unopened boxes of Cholestech cartridges must be stored in the Lipid Lab refrigerator. Once opened, boxes of Cholestech cartridges may be stored at room temperature for up to six months.

Appendix G: **Weight Related Eating Questionnaire (WREQ) (53)**

Directions: Please choose a response that best expresses how well each statement describes you.

1. I purposefully hold back at meals in order not to gain weight.
2. I tend to eat more when I am anxious, worried, or tense.
3. I count calories as a conscious means of controlling my weight.
4. When I feel lonely I console myself by eating.
5. I tend to eat more food than usual when I have more available places that serve or sell food.
6. I tend to eat when I am disappointed or feel let down.
7. I often refuse foods or drinks offered because I am concerned about my weight.
8. If I see others eating, I have a strong desire to eat too.
9. Some foods taste so good I eat more even when I am no longer hungry.
10. When I have eaten too much during the day, I will often eat less than usual the following day.
11. I often eat so quickly I don't notice I'm full until I've eaten too much.
12. If I eat more than usual during a meal, I try to make up for it at another meal.
13. When I'm offered delicious food, it's hard to resist eating it even if I've just eaten.
14. I eat more when I'm having relationship problems.
15. When I'm under a lot of stress, I eat more than I usually do.

16. When I know I'll be eating a big meal during the day, I try to make up for it by eating less before or after that meal.

A.1. Scoring protocol

WREQ scale scores are calculated as the average of the summed item raw scores by the following criteria: Not at all=1; Slightly=2; More or Less=3; Pretty Well=4; Completely=5.

Routine Restraint=(Item 1+Item 3+Item 7)/3.

Compensatory Restraint=(Item 10+Item 12+Item 16)/3.

Susceptibility to External Cues = (Item 5 + Item 8 + Item 9 + Item 11 + Item 13)/5.

Emotional Eating = (Item2+Item4+Item6+Item14+Item15)/5.

Appendix H: **Workbook Topics**

Table 1: Week Topics for Manualized Intervention	
1	Negative energy balance: increasing physical activity; reducing bite count and bite frequency; goal setting
2	Tips for increasing steps; reducing bite size & bite frequency
3	Increasing activities of daily living; lowering energy density of foods
4	Adding new activities; adding long pauses & appetite awareness
5	Overcoming exercise barriers; reducing liquid kcals, lowering kcals per bite (size/density)
6	Incorporating exercise in routines; fewer, slower, smaller bites
7	Less sedentary behavior; overcoming barriers to slower eating and fewer smaller bites
8	Review of concepts and plans for maintenance and continued progress

Appendix I: **Bite and Step Goal Sheets**

Bite Count Record and Goal Setting Sheet

Please wear the ELMM device for the rest of the day and record the total number of bites under Day 0 just to get used to the process. For the next three days (Days 1, 2 and 3), record the total number of bites at the end of each day. Next, look at the chart on page 2 to help set your new bite count goal. Your goal should be about 20% below your usual intake, which you are estimating from Days 1, 2 and 3. Write the goal for Day 4 on the chart. On Day 4, record your bites and compare to your goal. If your goal was too hard, chose a higher bite count goal for Day 5. If your goal was too easy, choose a lower bite count goal for Day 5. Repeat as needed until you have a goal that works for you.

	Day 0	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Today's Bite Count								
Daily Bite Count Goal	**X**	**X**	**X**	**X**				

The formula to calculate **average number of bites for 3 day** is =

$$\frac{\text{Total no of bites for 3 day}}{3}$$

Total number of Bites/3day	**Average number of bites/3Day**

Total Daily Bite Count (Baseline)	Bite Count Goal for Remainder of Study (25%)	Bite Count Goal for Remainder of Study (20%)
≤75	56	60
76-80	59	62
81-85	62	66
86-90	66	70
91-95	70	74
96-100	74	78
101-105	77	82
106-110	81	86
111-115	85	90
116-120	89	94
121-125	92	98
126-130	96	102
131-135	100	106
136-140	104	110
141-145	107	114
146-150	111	118
151-155	115	122
156-160	119	126
161-165	122	130
166-170	126	134
171-175	130	138
176-180	134	142
181-185	137	146
186-190	141	150
191-195	145	154
196-200	149	158
201-205	152	162
206-210	156	166
211-215	160	170
216-220	164	174
221-225	167	178
226-230	171	182
231-235	175	186
236-240	179	190
241-245	182	194
246-250	186	198
251-255	190	202
256-260	194	206
261-265	197	210
265-270	200	213
271-275	205	218
276-280	209	222
281-285	212	226
286-290	216	230
291-295	220	234
296-300	224	238

Step Count Record and Goal Setting Sheet

Please wear the ELMM device for the rest of the day and record the total number of steps under Day 0 just to get used to the process. For the next three days (Days 1, 2 and 3), record the total number of steps at the end of each day. Next, look at the chart on page 2 to help set your new step count goal. Your goal should be about 20% above your usual number of steps, which you are averaging from Days 1, 2 and 3. Write the goal for Day 4 on the chart. On Day 4, record your steps and compare to your goal. If your goal was too hard, choose a lower step count goal for Day 5. If your goal was too easy, choose a higher step count goal for Day 5. Repeat as needed until you have a goal that works for you.

	Day 0	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Today's Step Count								
Daily Step Count Goal	**X**	**X**	**X**	**X**				

Day 1 + Day 2 + Day 3 = _______________ total number of steps

AVERAGE OF THREE DAYS =

Total number of steps for Days 1, 2 and 3=

3

___________________ AVERAGE NUMBER OF STEPS

Total number of Steps/3day	**Average number of Steps/3Day**

Total Daily Step Count (Baseline)	Step Count Goal for Remainder of Study
500-1000	600-1200
1001-1500	1201-1800
1501-2000	1801-2400
2001-2500	2401-3000
2501-3000	3001-3600
3001-3500	3601-4200
3501-4000	4201-4800
4001-4500	4801-5400
4501-5000	5401-6000
5001-5500	6001-6600
5501-6000	6601-7200
6001-6500	7201-7800
6501-7000	7801-8400
7001-7500	8401-9000
7501-8000	9001-9600
8001-8500	9601-10,200
8501-9000	10,201-10,800
9001-9500	10,801-11,400
9501-10,000	11,401-12,000
10,001-10,500	12,001-12,600
10,501-11,000	12,601-13,200
11,001-11,500	13,201-13,800
11,501-12,000	13,801-14,400
12,001-12,500	14,401-15,000
12,501-13,000	15,001-15,600
13,001-13,500	15,601-16,200
13,501-14,000	16,201-16,800
14,001-14,500	16,801-17,400
14,501-15,000	17,401-18,000
15,001-16,000	18,001-19,200
16,001-16,500	19,201-19,800
16,501-17,000	19,801-20,400
17,001-17,500	20,401-21,000
17,501-18,000	21,001-21,600

Appendix J: **Queen's College Step Test**

Steps to Conduct the Submaximal Bench Step Test*

EQUIPMENT

- Step—41.3 cm (16.25 in) high for men and women
- Metronome
- Stopwatch
- Individual data sheets

Step 1: Have the participant sit on the bench step and rest for 3 min, after which the tester should palpate the radial pulse for 15 s and record the resting HR.

Step 2: Set the metronome at 88 beats · min−1 to allow the participant to make contact with a foot on each beep in an up-up-down-down manner. This cadence results in the necessary 22 steps · min−1 necessary for the test on women. For men, set the metronome at 96 beats · min−1 and thus 24 steps · min−1.

Step 3: When the participant is ready, begin the 3 min test and start the stopwatch (see figure 7.3a).

Step 4: To avoid muscle fatigue, the participant should switch the leading leg at least once during the test.

Step 5: After exactly 3 min of stepping, the participant should stop. The tester should palpate for the radial pulse (see figure 7.3b). Begin counting at exactly 3:05 and count for 15 s (i.e., to 3:20).

Step 6: Calculate the predicted VO2max by using the recovery HR in the equations below, where HR is beats · min−1.

Men: VO2max (ml · kg−1 · min−1) = 111.33 - (0.42 Å~ HR)
Women: VO2max (ml · kg−1 · min−1) = 65.81 - (0.1847 Å~ HR)

Step 9: Record data on the individual data sheet.

<u>Individual Data Sheet</u>
Name or ID number____ Date: __________________

Tester: ____ Time: _________________

Sex: M / F (circle one) Age: ________ y Height: _____________ in.

_________________ cm

Weight: ___________ lb. ____________ kg
Temperature: _____________ °F _____________ °C
Barometric pressure: ___________ mmHg Relative humidity:
_________________________ %

Raw Data
Age-predicted HRmax: ____________ beats · min−1

Resting 15 s pulse: ____________ Resting HR: ____________ beats · min−1
3:05 to 3:20 pulse count: ____________ Recovery HR: ____________ beats · min−1

VO2max Determination:
Men: VO2max (ml · kg−1 · min−1) = 111.33 - (0.42 Å~ HR)
Women: VO2max (ml · kg−1 · min−1) = 65.81 - (0.1847 Å~ HR)

**adapted from www.HumanKinetics.com/LaboratoryManualForExercisePhysiology*

***Appendix K:* Standardized Emails to Participants**

Weekly reminder for control group:

Thank you for participating in the ELMM Study! We hope that you are doing well, and want to remind you to keep up with your workbook. Any questions that you have can be sent to elmmstudy@gmail.com.

Weekly reminder for experimental group:

Thank you for participating in the ELMM Study! We hope that you are doing well, and want to remind you to keep up with your workbook, and to download your Bite Counter data each day. Please be sure to send your weekly data to us via email at elmmstudy@gmail.com. Any questions that you have can also be sent to elmmstudy@gmail.com.

Standardized email for questions that cannot be answered to maintain internal validity:

We thank you for your time and participation in this study. We are able to address many of your questions, but the answers to some questions may interfere with the ability of the study to be effective. Please be reassured that all of your questions will be answered at the completion of the study.

Appendix L: **Protocol for Participant Data Not Received**

If no data are received from a participant at the end of the week, the research team will send the following email:

Thank you for participating in the ELMM Study! We hope that you are doing well, and want to remind you to download your Bite Counter data each day. Please be sure to send your weekly data to us via email at elmmstudy@gmail.com. Any questions that you have can also be sent to elmmstudy@gmail.com.

If no data are received after two days, the research team will send the following email:

Thank you for participating in the ELMM Study! We hope that you are doing well, and want to let you know we have not yet received your data from last week. Please download and send it to us as soon as possible. If you are having any difficulty, please email us at elmmstudy@gmail.com so that we can assist you. Any questions that you have can also be sent to elmmstudy@gmail.com.

If no data are received two days after the previous email has been sent, attempt will be made by the research team to contact the participant by phone using the following script:

We would like to thank you for your participation in the ELMM Study. We have not yet received your data from last week, and doing so is a critical part of the study. Please let us know if you are having any difficulty in sending us your data, and we will be happy to assist you.

Appendix M: **Intuitive Eating Scale-2 (107, 118)**

Intuitive Eating Scale-2

For each item, please circle the answer that best characterizes your attitudes or behaviors.

1. I try to avoid certain foods high in fat, carbohydrates, or calories.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

2. I find myself eating when I'm feeling emotional (e.g. anxious, depressed, sad), even when I'm not physically hungry.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

3. If I am craving a certain food, I allow myself to have it.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

4. I get mad at myself for eating something unhealthy.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

5. I find myself eating when I am lonely, even when I'm not physically hungry.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

6. I trust by body to tell me when to eat.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

7. I trust my body to tell me what to eat.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

8. I trust my body to tell me how much to eat.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

9. I have forbidden foods that I don't allow myself to eat.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

10. I use food to help me soothe my negative emotions.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

11. I find myself eating when I am stressed out, even when I'm not physically hungry.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

12. I am able to cope with my negative emotions (e.g. anxiety, sadness) without turning to food for comfort.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

13. When I am bored, I do NOT eat just for something to do.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

14. When I am lonely, I do NOT turn to food for comfort.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

15. I find other ways to cope with stress and anxiety than by eating.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

16. I allow myself to eat what food I desire at the moment.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

17. I do NOT follow eating rules or dieting plans that dictate what, when, and/or how much to eat.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

18. Most of the time, I desire to eat nutritious foods.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

19. I mostly eat foods that make my body perform efficiently (well).

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

20. I mostly eat foods that give my body energy and stamina.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

21. I rely on my hunger signals to tell me when to eat.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

22. I rely on my fullness (satiety) signals to tell me when to stop eating.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

23. I trust my body to tell me when to stop eating.

_1=Strongly Disagree _2=Disagree _3=Neutral _4=Agree _5=Strongly Agree

Scoring:

Reverse scores (items 1, 2, 4, 5, 9, 10, 11): Strongly Disagree = 5, Disagree =4, Neutral =3, Agree = 2, Strongly Agree = 1. All other items attract positive scores: Strongly Disagree = 1, Disagree =2, Neutral =3, Agree = 4, Strongly Agree = 5.

Subscale	**Unconditional Permission to Eat**	**Eating for Physical Rather Than Emotional Reasons**	**Reliance on Internal Hunger/Satiety Cues**	**Body-Food Choice Congruence**	**Total score**
Items	1, 3, 4, 9, 19, 17	2, 5, 10, 11, 12, 13, 14, 15	6, 7, 8, 21, 22, 23	18, 19, 20	1-23
Total score for these items (keeping reverse scoring code as above)					
Divide by	**6**	**8**	**6**	**3**	**23**
Final scores					

Appendix N: **Indirect Calorimetry (Vmax, Sensormedics, Yorba, CA, USA)**

Protocol

1. Advise participant the day prior to IC testing to maintain normal diet and activities of daily living, abstain from alcohol and strenuous exercise at least 24 hours prior to testing and to restrict caffeine for at least 18 hours prior to testing. This is in addition to the 10 hour fast, except for water, prior to testing. Encourage the participant to exert as little energy as possible to come into the lab the next day; encourage driving or obtaining a ride to campus if possible, and discourage walking/biking to visit.
2. Ask the participant to void his/her bladder; lead to restroom if unfamiliar with building to avoid excess walking.
3. Upon participant's return to the lab, ask participant to complete IES Questionnaire.
4. Lead participant into the adjoining climate controlled metabolic testing lab.
5. Ask the participant if he/she has any questions before beginning procedure/testing.
6. Ask participant to lie in an elevated supine position on the laboratory bed and remain in a resting position, lying still, for 30 minutes. Ask the participant to refrain from reading, sleeping, writing, listening to music, or using cell phone, iPad or laptop in any way. Do not permit participant to hold any materials in his/her hands. Ensure that the laboratory is quiet, and provide participant with

blankets for comfort. Monitor participants closely to assure compliance with the protocol.

7. Collect flow rate and gas calibrations using two calibration tanks containing different CO_2 and O_2 concentrations, as directed by the manufacturer's instructions.
8. Ask participants to remain still while a 45-minute measurement is taken of resting EE and respiratory exchange ratio (RER; VCO_2/VO_2) by ventilated hood indirect calorimetry.
9. Upon completion of testing, ask participant to sit up slowly and escort him/her to the main EBL lab adjacent to the metabolic testing lab.
10. Offer participant a light snack and beverage and answer any questions about the testing procedure.

Appendix O (1). Experimental Biology Conference 2017 Poster Presentation.

Examining normative values in wearable device bite count data from a one-week free-living intervention

Jacqueline Beatty, Gregory Mayette, Geoffrey Greene, Kathleen Melanson
The University of Rhode Island
Poster # LB362 Experimental Biology 2017 jbeatty@uri.edu

Abstract # 9234

Background: Overweight and obesity remain prevalent in the United States with an estimated 67% of adults having a body mass index (BMI) over 25 kg/m^2. Wearable technology can provide self-monitoring and feedback, which have been shown to be beneficial in weight loss and maintenance. The Bite Counter® can be worn like a watch and has been validated in previous studies to be an effective tool in counting the number of bites taken by the user. Data analysis of this novel device requires the application of normative value parameters, previously established by creators of the device. Such parameters should be tested. **Methods:** Raw bite count data was analyzed from a study in which nineteen college-aged men and women (19.71 ± 1.59 years and BMI of 29.03 ± 3.40 kg/m^2) completed a one-week intervention testing the efficacy of the Bite Counter® in establishing a bite count goal and reducing bite count. Days in which subjects used the Bite Counter in their own free-living environment, with no supervision, were analyzed. Eating occasions with fewer than 4 bites, and those that lasted 3600 seconds (automatic shut off time of device), were removed; additionally, raw data were transformed to *z* scores, and scores greater than 3.29 were removed to account for outliers within subject variability. **Results:** Raw data and post-transformation scores were compared using paired *t* tests, and significant differences were found between total bites consumed ($p<.006$), total meal duration ($p<.005$), and eating rate as measured by bites per minute ($p=.038$). **Conclusion:** These analyses may help future researchers more effectively interpret data from bite-counting wearable technology.

Introduction

- Obesity has increased in the United States 0.6% each year between 2005 and 2012[1].
- Self-monitoring is a key component of successful weight loss, and the importance of self-monitoring behaviors in weight loss has been established[2,3].
- New technologies are available that hold promise for self-monitoring weight loss behaviors, but many of these devices are new to the market and to researchers analyzing these data.
- The Bite Counter has been found to detect 94% of bites in controlled laboratory settings and 86% of bites in free-living settings[4].
- The application of normative value parameters to this new type of data has yet to be explored.

Objectives

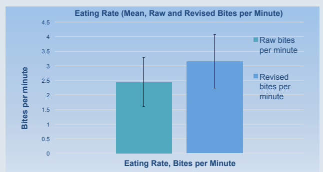
- To test the application of normative value parameters to a novel dataset of free-living bite count data.
- To determine if significant differences exist between pre-analyzed and post-analyzed bite count data, and to explore the potential impact of such differences in data analysis.

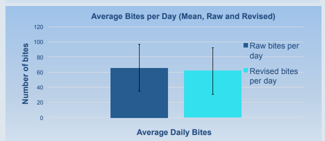
Materials & Methodology

- Data analysis in a study with overweight college students who participated in a bite count intervention.
- Subjects wore the Bite Counter® for one week in free-living settings.
- Eating occasion exclusion criteria:
  - Occasions with fewer than 4 bites
  - Occasions with 3600 seconds (automatic shut-off time of device)
  - *Z*-score transformation scores greater than 3.29
- Means and frequencies were used for demographics, and paired *t* tests compared raw and post-transformation scores using SPSS 24.

The Bite Counter [5]

Results





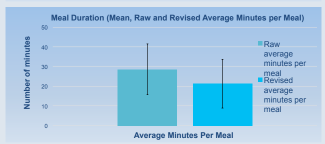


Table 1. Subject Characteristics

N = 19	
Age (years, M±SD)	19.53 ± 1.3
Gender* (n,% female)	16 (84%)
Race* (n, % Caucasian)	16 (89%)
BMI (kg/m²)	29.03 ± 3.4
Body Fat (%)	34.8 ± 6.4

*n=18

Table 2. Raw vs. Adjusted Data

	Raw	***Revised***	***p value***
Bites per minute, M±SD	2.44 ±0.92	3.15 ±0.84	0.038*
Average bites per day, M±SD	65.65 ±31.03	61.48 ±30.88	0.006*
Average minutes per eating occasion, M±SD	28.65 ±12.84	21.26 ±12.40	0.005*

Results

- After application of normal value parameters:
  - Average bites per day were significantly lower (p<.006)
  - Total meal duration was significantly lower (p<.005)
  - **Eating rate as measured in bites per minute was significantly higher (p=.038)**

Conclusions

- The application of normative value parameters to raw data leads to significant differences in total bite count, total meal duration and eating rate.
- Researchers can apply these parameters to raw data to adjust data to reflect more realistic usage of a wearable device.
- **Eating rate may be underestimated in eating occasions from free-living conditions if normal value parameters are not applied to raw data.**

Major References

1. Johnson NB, Hayes LD, Brown K, Hoo EC, Ethier KA. CDC National Health Report: leading causes of morbidity and mortality and associated behavioral risk and protective factors--United States, 2005-2013. MMWR Suppl 2014;63(4):3-27.
2. Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation 2014;129(25 Suppl 2):S102-38. doi: 10.1161/01.cir.0000437739.71477
3. Wing RR, Phelan S. Long-term weight loss maintenance. Am J Clin Nutr 2005;82(1 Suppl):222S-5S.
4. Dong YJ, Hoover A, Scisco J, Muth E. A new method for measuring meal intake in humans via automated wrist motion tracking. Appl Psychophys Biof 2012;37(3):205-15. doi: 10.1007/s10484-012-9194-1
5. icountbites.com /events.html

THE UNIVERSITY OF RHODE ISLAND

Nutrition and Food Sciences Department
Fogarty Hall, Kingston, RI

Appendix O (2). Experimental Biology Conference 2017 Abstract.

Examining normative values in wearable device bite count data from a two-week free-living intervention.

J. Beatty, G. Mayette, G. Greene, K. Melanson

Nutrition and Food Sciences Department, The University of Rhode Island, Kingston, RI

Overweight and obesity remain prevalent in the United States with an estimated 67% of adults having a body mass index (BMI) over 25 kg/m^2. Wearable technology can provide self-monitoring and feedback, which have been shown to be beneficial in weight loss and maintenance. The Bite Counter® can be worn like a watch and has been validated in previous studies to be an effective tool in counting the number of bites taken by the user. Data analysis of this novel device requires the appliance of normative value parameters, previously established by creators of the device. Such parameters should be tested. Raw bite count data was analyzed from a study in which nineteen college-aged men and women (19.71 ± 1.59 years and BMI of 29.03 ± 3.40 kg/m^2) completed a two-week intervention testing the efficacy of the Bite Counter® in establishing a bite count goal and reducing bite count. Days in which subjects used the Bite Counter in their own free-living environment, with no supervision, were analyzed. Eating occasions with fewer than 4 bites, and those that lasted 3600 seconds (automatic shut off time of device), were removed; additionally, raw data were transformed to *z* scores, and scores greater than 3.29 were removed to account for outliers within subject variability. Raw data and post-transformation scores were compared using paired *t* tests, and significant differences were found between total bites consumed ($p<.006$), total meal duration ($p<.005$), and eating rate as measured by

bites per minute (p=.038). These analyses may help future researchers more effectively interpret data from bite-counting wearable technology.

Funding: The University of Rhode Island Council for Research Grant, July 2015.

Appendix P. Seven Day Physical Activity Recall.

The Seven-Day Recall

PAR#: 1 2 3 4 5 6 7 Participant____________________

Interviewer________________ Today is________________ Today's Date_____

1. Were you employed in the last seven days? **0. No** (Skip to **Q#4**) 1. **Yes**
2. How many days of the last seven did you work? ____ days
3. How many total hours did you work in the last seven days? ____ hours last week
4. What two days do you consider your weekend days? ________ ________ (mark days below with a squiggle)

WORKSHEET **DAYS**

	SLEEP	1 __	2 __	3 __	4 __	5 __	6 __	7 __
MORNING	**Moderate**							
	Hard							
	Very Hard							
AFTERNOON	**Moderate**							
	Hard							
	Very Hard							
EVENING	**Moderate**							
	Hard							
	Very Hard							
Total Min Per Day	**Strength:** **Flexibility:**	____	____	____	____	____	____	____

4a. Compared to your physical activity over the past three months, was last week's physical activity more, less or about the same?
1. More
2. Less
3. About the same

Worksheet Key:	**Rounding:**	
	10-22 min.=.25	1:08-1:22 hr/min.=1.25
An asterisk (*) denotes a work-related activity.	23-37 min.=.50	
A squiggly line through a column (day) denotes a weekend day.	38-52 min.=.75	
	53-1:07 hr/min. =1.0	

Appendix Q (1). Consent Form: ELMM Study.

Department of Nutrition and Food Science
123 Fogarty Hall
Kingston, RI 02881
Title of Project: A Scalable Intervention Tracking Three Weight-Related Behaviors with a Single Device
The Eat Less, Move More Study Consent Form

CONSENT FORM FOR RESEARCH

You have been invited to take part in a research project described below. The researcher will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, Kathleen Melanson, the person primarily responsible for this study [Phone: (401) 874-4477], will discuss them with you. You must be between the ages of eighteen and sixty years old to participate in this study.

Exclusionary criteria

- Smokers
- BMI of less than 27 mg/kg^2 or greater than 37 mg/kg^2
- Age of less than 18 or greater than 60 years
- Documented eating disorder
- Chronic metabolic disease, such as diabetes or kidney disease
- Use of prescription or over-the-counter medications that affect appetite or energy expenditure
- Pregnant or lactating women

Description of the project:

This study will involve research using the Bite Counter, a device that counts the number of bites of food taken during a meal. The purpose of this research study is to determine the effects of wearing the Bite Counter on weight, body composition, lean body mass and fitness level. The amount of time required for participation is about 8 hours in total, in 3 lab visits over approximately 8 weeks. It also involves a total of 4 telephone interviews about diet and activity over the 8 weeks.

What will be done?

If you decide to take part in this study, here is what will happen over the course of three visits (the first visit will be approximately 45 minutes and the second and third visits will be approximately two and a half hours), totaling a lab time commitment of about 8 hours:

You will first complete a participant screening over the phone to determine if you meet the inclusion criteria.

- During the first visit to the lab, a researcher will sit with you to review the informed consent form, and answer your questions. Your height and weight will be taken to confirm that the measurements you provided us in the phone screening are accurate. These measurements will be used to determine if you meet the body mass index (BMI) criteria for the study. **You will be assigned to one of two groups in the study: one group will receive the weight loss intervention, and the other will receive the weight loss intervention and the Bite Counter. Please note that you may not be assigned to the group with the Bite Counter; however, your participation in the study is just as important**. You will be asked to give a 24 hour dietary recall as well as a 24 hour physical activity recall.

- During the following week before visit two, you will be contacted via telephone and asked to give two 24-hour dietary recalls and two 24-hour physical activity recalls over the phone.

- For lab visit two, you will come to the lab after a 10 hour, overnight fast. After your blood pressure has been measured, your height, weight and waist circumference measurements will be taken again, and body composition will be tested using the Bod Pod following standardized procedures.* You will then have your blood pressure taken using standardized procedures, have a finger stick blood sample taken to measure your fasting glucose and blood lipid levels, and you will then be served a test breakfast in the lab. After the meal, you will be asked to fill out two questionnaires, and you will be asked to give in-person 24-hour dietary and physical activity recalls. You will then be introduced to the weight loss intervention. Finally, you will be asked to perform a standardized three minute step fitness test.

- Visit two will be scheduled after visit one depending on the time frame relating to the female menstrual cycle if applicable. During the last week of the intervention, you will again be contacted via telephone and asked to give two 24-hour dietary recalls and two 24-hour physical activity recalls over the phone.

- Visit three will take place eight weeks after visit two. For lab visit three, you will come to the lab after a 10 hour, overnight fast. After your blood pressure has been measured, your height, weight and waist circumference measurements will be taken again, and body composition will be tested using the Bod Pod following standardized procedures. You will then have a finger stick blood sample taken to measure your fasting glucose and blood lipid levels, and you will then be served a test breakfast in the lab. After the meal, you will be asked to fill out two questionnaires, and you will be asked to give in-person 24-hour dietary and physical activity recalls. Finally, you will be asked to perform a standardized three minute step fitness test.

In an effort to thank you for your time, effort and participation in this study, you will be awarded a pro-rated stipend upon completion of each lab visit as follows: first visit: $20.00; second visit: $40.00; and third visit: $100.00. You must complete the study to receive your incentive.

* The Bod Pod is a research tool that can measure body composition by way of air displacement plethysmography. You will be asked to come into the lab in comfortable clothes with a swimsuit or fitted exercise clothes so that the Bod Pod can more accurately analyze your body composition. You will be asked to sit inside the Bod Pod for a few minutes while the measurements are taken, and the researcher will remain in the room with you the entire time.

Risks or discomfort:

There are minimal risks for the following procedures: questionnaires, consumption of a test meal, measures of height, weight, waist circumference, food intake, and appetite. Some minor discomfort may occur with those who are afraid of confined spaces when sitting in the Bod Pod for body composition testing. If you feel uncomfortable, the test will cease and you can exit the Bod Pod. The blood pressure cuff may cause a feeling of pressure on the upper arm. The finger prick may result in some slight, short term discomfort. Even though trained, experienced personnel will perform the blood draw using sterile technique, it is possible that minor bruising and infection may occur.

Benefits of this study:

The potential benefits to this research study also include obtaining data that may be insightful to eating habits, and potential mechanisms to lose weight. Participants will also receive their own physical and dietary measurements, including body composition results. The potential benefits to society include the possibility of further validation of a wearable device that will potentially help individuals control their eating rate, food intake and physical activity, thereby leading to a helpful, sustainable, low-effort way to achieve healthy weight loss. The research has the potential to provide a valuable piece to weight loss programs, and may help address the need for long-term, sustainable results.

Confidentiality:

Your part in this study is confidential. The information you provide to us will be identified using a code, not your name. This information, which includes a paper copy of each informed consent form, will be stored in a locked file cabinet in the Energy Balance Lab in Fogarty Hall, to which only the researchers and research assistants will have a key. In addition, the Energy Balance Lab is locked when lab researchers and assistants are not present and only researchers and assistants possess a key to the lab. The electronic version of any private information will be stored on the computer in the lab to which only lab researchers and assistants have the login and password information.

This study is using an investigational device; therefore please be advised that the Food and Drug Administration has the privilege of inspecting study data with your identifying information.

In case there is any injury to the subject: (If applicable)
If this study causes you any injury, you should write or call Dr. Kathleen Melanson at the University of Rhode Island at (401) 874-4477, email: kmelanson@uri.edu. You may also call the office of the Vice President for Research and Economic Development, 70 Lower College Road, Suite 2, University of Rhode Island, Kingston, Rhode Island, telephone: (401) 874-4328.

Decision to quit at any time:
The decision to take part in this study is up to you. You do not have to participate. If you decide to take part in the study, you may quit at any time. Whatever you decide will in no way penalize you. If you wish to quit, simply inform Dr. Kathleen Melanson (see contact information above) of your decision.

Rights and Complaints:
If you are not satisfied with the way this study is performed, you may discuss your complaints with Dr. Kathleen Melanson, anonymously, if you choose. In addition, if you have questions about your rights as a research participant, you may contact the

office of the Vice President for Research and Economic Development, 70 Lower College Road, Suite 2, University of Rhode Island, Kingston, Rhode Island, telephone: (401) 874-4328.

You have read the Consent Form. Your questions have been answered. Your signature on this form means that you understand the information and you agree to participate in this study.

___________________________	___________________________
Signature of Participant	Signature of Researcher
___________________________	___________________________
Typed/printed Name	Typed/printed name
___________________________	___________________________
Date	Date

I give my permission to be contacted for future research studies.

___________________________	___________________________
Signature of Participant	Signature of Researcher
___________________________	___________________________

Date Date

Please sign both consent forms and keep one for your own records.

Appendix Q (2). Consent Form: PABA Study.

Department of Nutrition and Food Science
123 Fogarty Hall
Kingston, RI 02881
Title of Project: A Scalable Intervention Tracking Three Weight-Related Behaviors with a Single Device
Physiological and Behavioral Add-On Study Consent Form

CONSENT FORM FOR RESEARCH

You have been invited to take part in a research project described below. The researcher will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, Kathleen Melanson, the person primarily responsible for this study [Phone: (401) 874-4477], will discuss them with you. You must be between the ages of eighteen and sixty years old to participate in this study.

Exclusionary criteria

- Smokers
- BMI of less than 27 mg/kg^2 or greater than 37 mg/kg^2
- Age of less than 18 or greater than 60 years
- Documented eating disorder
- Chronic metabolic disease, such as diabetes or kidney disease
- Use of prescription or over-the-counter medications that affect appetite or energy expenditure
- Pregnant or lactating women

Description of the project:

This study will involve research using the Bite Counter, a device that counts the number of bites of food taken during a meal. The purpose of this research study is to determine the effects of wearing the Bite Counter on weight, body composition, lean body mass, fitness level **and resting metabolic rate**. The amount of time required for participation is about **11** hours in total, in **5** lab visits over approximately 8 weeks. It also involves a total of 4 telephone interviews about diet and activity over the 8 weeks.

What will be done?

If you decide to take part in this study, here is what will happen over the course of five visits (the first visit will be approximately 45 minutes; the second and fourth visits will be approximately two and a half hours, **and the third and fifth visits will take about one and a half hours each**), totaling a lab time commitment of about **11** hours:

You will first complete a participant screening over the phone to determine if you meet the inclusion criteria.

- ❖ During the first visit to the lab, a researcher will sit with you to review the informed consent form, and answer your questions. Your height and weight will be taken to confirm that the measurements you provided us in the phone screening are accurate. These measurements will be used to determine if you meet the body mass index (BMI) criteria for the study. **You will be assigned to one of two groups in the study: one group will receive the weight loss intervention, and the other will receive the weight loss intervention and the Bite Counter. Please note that you may not be assigned to the group with the Bite Counter; however, your participation in the study is just as important**. You will be asked to give a 24 hour dietary recall as well as a 24 hour physical activity recall.

- ❖ During the following week before visit two, you will be contacted via telephone and asked to give two 24-hour dietary recalls and two 24-hour physical activity recalls over the phone.

- ❖ For lab visit two, you will come to the lab after a 10 hour, overnight fast. After your blood pressure has been measured, your height, weight and waist circumference measurements will be taken again, and body composition will be tested using the Bod Pod following standardized procedures.* You will then have your blood pressure taken using standardized procedures, have a finger stick blood sample taken to measure your fasting glucose and blood lipid levels, and you will then be served a test breakfast in the lab. You will be asked to fill out four appetite measurement scales. After the meal, you will be asked to fill out two questionnaires, and you will be asked to give in-person 24-hour dietary and 7-day physical activity recalls. You will then be introduced to the weight loss intervention. Finally, you will be asked to perform a standardized three minute step fitness test.

- **Lab visit three will take place one day after visit two, and you will be asked to fast for 10 hours overnight before returning to the lab the next morning. You will be asked to exert as little energy as possible to get into the lab; therefore, it will be suggested that you drive or get a ride to campus as opposed to walking or biking to campus. Upon arrival, you will be escorted to the indirect calorimeter lab and asked to rest in a supine position for 30 minutes before testing. The researcher will place a mask that is connected to the indirect calorimeter so that your breaths can be measured and analyzed by the calorimeter. This testing will take about 4 minutes during which you will be asked to lie still and continue to relax. After testing, you will be asked to fill out three questionnaires relating to sleep and eating habits.**

- During the last week of the intervention, you will again be contacted via telephone and asked to give two 24-hour dietary recalls and two 24-hour physical activity recalls over the phone.

- Visit four will take place eight weeks after visit two. For lab visit four, you will come to the lab after a 10 hour, overnight fast. After your blood pressure has been measured, your height, weight and waist circumference measurements will be taken again, and body composition will be tested using the Bod Pod following standardized procedures. You will then have a finger stick blood sample taken to measure your fasting glucose and blood lipid levels, and you will then be served a test breakfast in the lab. You will be asked to fill out four appetite measurement scales. After the meal, you will be asked to fill out two questionnaires, and you will be asked to give in-person 24-hour dietary and 7-day physical activity recalls. Finally, you will be asked to perform a standardized three minute step fitness test.

- **Lab visit five will take place one day after visit four, and you will be asked to fast for 10 hours overnight before returning to the lab the next morning. You will be asked to exert as little energy as possible to get into the lab; therefore, it will be suggested that you drive or get a ride to campus as opposed to walking or biking to campus. Upon arrival, you will be escorted to the indirect calorimeter lab and asked to rest in a supine position for 30 minutes before testing. The researcher will place a mask that is connected to the indirect calorimeter so that your breaths can be measured and analyzed by the calorimeter. This testing will take about 4 minutes during which you will be asked to lie still and continue to relax. After testing, you will be asked to fill out three questionnaires relating to sleep and eating habits.**

* The Bod Pod is a research tool that can measure body composition by way of air displacement plethysmography. You will be asked to come into the lab in comfortable clothes with a swimsuit or fitted exercise clothes so that the Bod Pod can more accurately analyze your body composition. You will be asked to sit inside the Bod Pod for a few minutes while the measurements are taken, and the researcher will remain in the room with you the entire time.

Risks or discomfort:

There are minimal risks for the following procedures: questionnaires, consumption of a test meal, measures of height, weight, waist circumference, food intake, and appetite. Some minor discomfort may occur with those who are afraid of confined spaces when sitting in the Bod Pod for body composition testing **or using the mask for indirect calorimetry measurement.** If you feel uncomfortable, the test will cease and you can exit the Bod Pod **or we can remove the indirect calorimeter mask**. The blood pressure cuff may cause a feeling of pressure on the upper arm. The finger prick may result in some slight, short term discomfort. Even though trained, experienced personnel will perform the blood draw using sterile technique, it is possible that minor bruising and infection may occur.

Benefits of this study:

In an effort to thank you for your time, effort and participation in this study, you will be awarded a pro-rated stipend upon completion of each lab visit as follows: first visit: $20.00; second visit: $40.00; **third visit, $20.00;** fourth visit: $100.00; **and fifth visit, $20.00.** The potential benefits to this research study also include obtaining data that may be insightful to eating habits, and potential mechanisms to lose weight. Participants will also receive their own physical and dietary measurements, including body composition **and resting metabolic rate** results. The potential benefits to society include the possibility of further validation of a wearable device that will potentially help individuals control their eating rate, food intake and physical activity, thereby leading to a helpful, sustainable, low-effort way to achieve healthy weight loss. The research has the potential to provide a valuable piece to weight loss programs, and may help address the need for long-term, sustainable results.

Confidentiality:

Your part in this study is confidential. The information you provide to us will be identified using a code, not your name. This information, which includes a paper copy of each informed consent form, will be stored in a locked file cabinet in the Energy

Balance Lab in Fogarty Hall, to which only the researchers and research assistants will have a key. In addition, the Energy Balance Lab is locked when lab researchers and assistants are not present and only researchers and assistants possess a key to the lab. The electronic version of any private information will be stored on the computer in the lab to which only lab researchers and assistants have the login and password information.

This study is using an investigational device; therefore please be advised that the Food and Drug Administration has the privilege of inspecting study data with your identifying information.

In case there is any injury to the subject: (If applicable)
If this study causes you any injury, you should write or call Dr. Kathleen Melanson at the University of Rhode Island at (401) 874-4477, email: kmelanson@uri.edu. You may also call the office of the Vice President for Research and Economic Development, 70 Lower College Road, Suite 2, University of Rhode Island, Kingston, Rhode Island, telephone: (401) 874-4328.

Decision to quit at any time:
The decision to take part in this study is up to you. You do not have to participate. If you decide to take part in the study, you may quit at any time. Whatever you decide will in no way penalize you. If you wish to quit, simply inform Dr. Kathleen Melanson (see contact information above) of your decision. You must complete the study, however, to receive your incentive.

Rights and Complaints:
If you are not satisfied with the way this study is performed, you may discuss your complaints with Dr. Kathleen Melanson, anonymously, if you choose. In addition, if you have questions about your rights as a research participant, you may contact the office of the Vice President for Research and Economic Development, 70 Lower

College Road, Suite 2, University of Rhode Island, Kingston, Rhode Island, telephone: (401) 874-4328.

You have read the Consent Form. Your questions have been answered. Your signature on this form means that you understand the information and you agree to participate in this study.

__________________________	__________________________
Signature of Participant	Signature of Researcher
__________________________	__________________________
Typed/printed Name	Typed/printed name
__________________________	__________________________
Date	Date

Please sign both consent forms and keep one for your own records.

I give my permission to be contacted for future research studies.

__________________________	__________________________
Signature of Participant	Signature of Researcher

______________________________ ______________________________

Date Date

Appendix R (1). Protocol Checklists: ELMM Study.

ELMM Baseline Visit Day Protocol

When Participant Arrives:

1. ___ Greet participant, thank them for their interest in our study; tell them that we first need to verify their height and weight to measure their BMI; ask participant to empty their bladder if they haven't already
2. ___ Measure height and weight using Weight (and BMI) Assessment Protocol
3. ___ Record height and weight on Lab Screening Form and here:
    a. Ht: _________ Wt: __________
4. ___ Assess BMI with BMI Chart to ensure criteria is met BMI: _________
5. ___ Inform subject that they have/have not been assigned to the group with the ELMM, but that their participation in the study is important regardless of assignment to group
6. ___ Continue filling out Lab Screening Form; allow participants to fill out demographic section on their own
7. ___ If all criteria are met, continue to Step 8; if not, proceed to Step 14
8. ___ Go over informed consent form with participants; ensure understanding by having them summarize what is required of them for the duration of the study; have them sign two copies – one for themselves and one for their data folder. Researcher must sign both as well
9. ___ Explain 24-hour recall process and provide participant with portion size estimation pamphlet; let them know you will be asking information about approximate start and stop times of each meal as well as portion sizes and cooking methods of foods consumed; please take a moment to emphasize that the recalls require many questions about detail to ensure that we are able to collect the most accurate information for our research. This may require time and patience ☺
10. ___ Record availability time window for participant on form

11. ___ Provide UEM Test Meal Day Instructions Bod Pod Preparation Instructions and explain protocol as well as fasting for 10 hours prior to next lab visit
12. ___ Schedule Week 0 and Week 8 visits if not already scheduled
13. ___ Provide subject with $20 stipend and have him or her sign two copies and receipt; one for themselves and one for their data folder
14. ___ If screening criteria is not met, explain why, answer any questions, thank the subject for his/her interest, and ask if we can contact him/her for any future studies. If he/she knows of someone who may qualify, ask to please refer to us.
15. ___ If subject qualifies, take a moment to thank the subject for his/her participation and reiterate how much you appreciate his/her time and effort in this study.

24-hour Recall Protocol: two unannounced by phone

1. ___ Call participant; record all attempts on appropriate sheet
2. ___ Record food intake 24-hour recall collection form; record approximated start and stop times of meals; enter data in Food Processor SQL

ELMM Test Meal Day Week 0 Protocol

Morning of participant's Week 0 Visit:

1. ___ Turn on Bod Pod to warm up; run QC operations (calibrate Bod Pod and scale every 2 weeks)
2. ___ Ensure that Bod Pod scale is level
3. ___ Ensure that Bod Pod printer has paper and toner
4. ___ Ensure that lab scale is level
5. ___ Set out subject's file
6. ___ Record temperature of the UEM room on the data collection sheet
7. ___ Ensure that the ELMM has been calibrated and reset using the ELMM software – connect ELMM to computer using the USB cable and click on "ELMM" icon on desktop

Preparations before subject's arrival:

1. ____ Turn on the kitchen scale at least 20 minutes prior to calibration
2. ____ 10 minutes before subject's arrival:
    a. ____ Calibrate scale according to instructions posted above scale in kitchen
    b. ____ Record the weight of the spoon on the data collection sheet
    c. ____ Record the weight of the bowl on data collection sheet
    d. ____ Prepare the UEM station:
        i. ____ Turn on the computer; wait to proceed until the desktop appears.
        ii. ____ Turn on the UEM scale. Automatically calibrate it by pressing Cal/Menu.
        iii. ____ Open LabX light balance program (steps 1-7 in the UEM Protocol)
        iv. ____ Make sure table and placemat are clean
        v. ____ Set next to the placemat a napkin and the tablespoon

When subject arrives:

Greet the subject cheerfully, thank him or her for coming, and ask her if she has any questions before you begin.

1. ____ Check compliance with test day breakfast instructions. Subject cannot eat test meal unless these instructions were followed.
2. ____ Escort subject to Laboratory 205A for height, weight and waist circumference measurements following standardized procedures
3. ____ Record results: HEIGHT: ____ WEIGHT: ____ WC: ____
   HEIGHT: ____ WEIGHT: ____ WC: ____
   Average: HEIGHT: _________ WEIGHT: __________ WC: __________
4. ____ Perform Bod Pod testing following standardized procedures
5. ____ Record results: Body Fat Mass (lbs.): ___ Lean Body Mass(lbs.): _____
   % Body Fat Mass: __________ % Fat Free Mass: _________
   Body Mass: ____________
6. ____ Perform Cholestech testing, following standardized procedures

7. ____ Record results: GLUCOSE: _____ CHOL: _____ LDL: ______
    a. HDL: _____ TAG: _____ non-HDL: ______
8. ____ Check blood pressure following standardized procedures while waiting for Cholestech results to print
9. ____ Record results: BP: ____________ _____________ _____________
10. ____ Ask subject about use of wearable technology to monitor physical activity:
    a. Do you wear a device that helps you to monitor your physical activity?_________
    b. If YES, What is the brand/type? ___________
    c. How often do you wear the device?

        1-2 days/wk 3-4 days/wk 5-6 days/wk DAILY
11. ____ Make sure all results are recorded on data collection sheet including height, weight, waist circumference, Bod Pod percentages of pounds and percentages body fat and fat free mass, body mass, blood pressure, and blood glucose and lipid results, and wearable technology questions.
12. ____ Escort the subject back to the EBL
13. ____ Ask subject which flavor oatmeal he/she would prefer (maple brown sugar or cinnamon spice). Remind subject that flavor chosen must be served at next visit as well.
14. ____ Ask subject which beverage he/she would prefer: decaf coffee, decaf tea, or water (all unflavored and no milk or sweetener). Remind subject that beverage chosen must be served at next visit as well.
15. ____ Ask the subject void his or her bladder
16. ____ Make oatmeal breakfast following standardized recipe
17. ____ Prepare requested beverage
18. ____ Record flavor of oatmeal and type of beverage served
19. ____ Set timer for 60 minutes and put it by the UEM computer
20. ____ Ask the subject to complete the initial VAS satiety (before meal) sheet by marking a vertical line (not a circle or an X) in pencil at the appropriate point

on VAS sheet. Be sure to record the UEM computer clock time on the VAS sheet

21. ____ While subject is completing the VAS sheet
22. ____ Put the oatmeal on the UEM scale. Start the UEM (steps 7-9 in the UEM Protocol)
23. ____ Ask the participant if they have any questions before starting
24. ____ Escort the subject to the UEM station and have him or her sit down, push in chair, and adjust height to preference

Note: During test breakfasts-

1. Keep lab door closed; put the Test Meal In Progress sign on the outside of the door.

2. Close all doors and ensure that windows fully covered by darkening curtains.

3. Ensure that the subject is comfortable and not distracted during testing.

Say that this is a test breakfast of oatmeal. Water is available for you to drink during the meal, and you may have more if you finish what is in the cup. Please eat and drink as much as you like until you are comfortably full. Keep in mind, once you are finished with your meal, you will not be allowed to have any more to eat or drink for 1 hour. You will be required to stay in the lab for this hour after the first spoonful. I will be keeping track of the meal time for the VAS-Scales, so please ring the bell once right before you take your first spoonful (that is when you are putting your spoon into the meal for the first time to remove pasta to eat), and please ring the bell once when you are finished eating. If you would like more water, please ring the bell 2 quick times and we will bring you another cup.

*Keep in mind, the portion of oatmeal provided is the maximum amount each participant can have. Do not let the participant know this at the beginning of the meal.

<u>When meal begins:</u>

1. ____ When the subject rings the bell the first time (signaling the start of the test meal), record on the data collection sheet the time listed on the computer screen and start the **60-minute timer.**
2. **____ Make sure EBL is dark.**
3. ____ Record on the data collection sheet anything that was unusual in the observations table (ex. subject didn't like oatmeal, cleaned the plate, was feeling sick, didn't follow instructions, moved plate off of scale, used cell phone during meal; test meal preparation; UEM malfunctions).
4. ____ Monitor the LabX light program to ensure continuous UEM recording of the test breakfast.

<u>Upon meal completion:</u>

1. ____ When the subject rings the bell once a second time signaling that he or she is finished eating (signaling the end of the test meal), stop the UEM (step 10 in the UEM Protocol), record on the data collection sheet the time shown on the UEM computer screen, and **start a 20-minute timer.**
2. ____ Note the position of the spoon in the test meal area
3. ____ Escort the subject away from the UEM station. Administer VAS sheet for meal completion; have subject record the wall clock time on the VAS satiety sheet.
4. ____ Print the job report (step 11 in the UEM Protocol); label it with subject ID # and Visit #1. Remove the plate and cup(s) and put them in the kitchen.
5. ____ Inform the subject of the time left that she needs to remain in the lab (from the 60-minute timer).

6. ____ Conduct 24-hour recall #3 and record information on the 24-hour recall sheet. Give special attention to the start and stop times of each meal and record these times on the 24-hour recall sheet.
7. ____ Calculate the 20 minutes post-meal completion time point and record on the data sheet.
8. ____ Administer 20 minutes post meal completion VAS satiety sheet; have subject record the wall clock time on this sheet. If the 24-hour recall has not finished, pause to fill in the VAS sheet and continue the recall once sheet filled out.
9. ____ Administer 7-Day Physical Activity Recall (PAR).
10. ____ Administer the Weight-Related Eating Questionnaire.
11. ____ Administer 60 minutes post meal initiation VAS satiety sheet; have subject record the wall clock time on this sheet.
12. ____ Confirm date and time of Week 8 Visit with subject
13. ____ Tell the subject that he or she will be contacted by phone to obtain two 24-hour recalls during the seventh week of the intervention.
14. ____ Provide control group subjects with Intervention Workbook and provide experimental group subjects with Intervention Workbook AND ELMM AND ELMM manual.
15. ____ For control subjects, introduce the workbook and explain information from the introduction.
16. ____ For experimental subjects, introduce the workbook and explain information from the introduction. Additionally, introduce the ELMM, the charger, and demonstrate how to plug it into the computer.
17. ____ For experimental subjects, provide a demonstration on how to download the software and how to use it (refer subject to set of instructions within workbook).
18. ____ Provide subjects with a Bite Count, Step Count and Bite Count Interval Record/Goal sheets; explain how to fill out the records and select appropriate bite count goal.

19. ____ Highlight lab and researcher phone number and encourage subject to call if he/she has ANY difficulty downloading software or uploading and sending data as demonstrated.
20. ____ Deliver "This device works best when you see it as your friend, not your enemy" speech. Emphasize that the device can help with weight loss when used appropriately, and discuss the importance of setting realistic goals and the ability to adjust those goals if he/she finds the goals to be too difficult
21. ____ Emphasize that the alarm function should NOT be used, as it is contraindicated in following the proven intervention.
22. ____ Ensure participants will bring ELMM to Week 8 Visit.
23. ____ Conduct 3-minute Queens College Step Test following protocol.
24. ____ Record results of step test including pulse rate: __________________
25. ____ Subject will receive second $40 stipend and receipt; subject to sign TWO copies of receipt; one must be kept by researcher and placed in subject's file.
26. ____ Important: Implore continuation with the study: please take a moment to express sincere thanks for participating in the study. Please inform the subject that their contribution is critical not only to science and the field of nutrition, but to help a graduate student complete her research to meet her goal of graduating ☺. It is okay to really speak openly with the participant about this as completing the study is hard work and we really want them to know how important it is. Thank you!!

After subject leaves the lab:

1. ____ Measure the oatmeal and water/decaf coffee/decaf tea leftovers on the kitchen scale and record the exact weights on the data collection sheet. Make sure the kitchen door is closed during measurements.
2. ____ Complete the calculations for total oatmeal consumed and total drink consumed, and record them on the data collection sheet.
3. ____ Calculate the total time of the meal and record it on the data collection sheet.

4. ____ Add subject’s name, date and stipend payment to Excel ELMM Expense Report.
5. ____ File the subject’s folder and clean up.

ELMM Test Meal Day Week 8 Protocol

Morning of participant’s Week 8 Visit:

8. ___ Turn on Bod Pod to warm up; run QC operations (calibrate Bod Pod and scale every 2 weeks)
9. ___ Ensure that Bod Pod scale is level
10. ___ Ensure that Bod Pod printer has paper and toner
11. ___ Ensure that lab scale is level
12. ___ Set out subject’s file
13. ___ Record temperature of the UEM room on the data collection sheet
14. ___ Ensure that the ELMM has been calibrated and reset using the ELMM software – connect ELMM to computer using the USB cable and click on “ELMM” icon on desktop

Preparations before subject’s arrival:

3. ____ Turn on the kitchen scale at least 20 minutes prior to calibration
4. ____ 10 minutes before subject’s arrival:
    a. ____ Calibrate scale according to instructions posted above scale in kitchen
    b. ____ Record the weight of the spoon on the data collection sheet
    c. ____ Record the weight of the bowl on data collection sheet
    d. ____ Prepare the UEM station:
        i. ____ Turn on the computer; wait to proceed until the desktop appears.
        ii. ____ Turn on the UEM scale. Automatically calibrate it by pressing Cal/Menu.

iii. ____ Open LabX light balance program (steps 1-7 in the UEM Protocol)
iv. ____ Make sure table and placemat are clean
v. ____ Set next to the placemat a napkin and the tablespoon

When subject arrives:

Greet the subject cheerfully, thank him or her for coming, and ask her if she has any questions before you begin.

25. ____ Check compliance with test day breakfast instructions. Subject cannot eat test meal unless these instructions were followed.
26. ____ Escort subject to Laboratory 205A for height, weight and waist circumference measurements following standardized procedures
27. ____ Record results: HEIGHT: _____ WEIGHT: _____ WC: ______
HEIGHT: _____ WEIGHT: ______ WC: ______
Average: HEIGHT: _______ WEIGHT: ________ WC: ________
28. ____ Perform Bod Pod testing following standardized procedures
29. ____ Record results: Body Fat Mass (lbs.): ____ Lean Body Mass(lbs.): _____
% Body Fat Mass: _____ % Fat Free Mass: _____ Body Mass: _____
30. ____ Perform Cholestech testing, following standardized procedures
31. ____ Record results: GLUCOSE: ______ CHOL: ______ LDL: _______
    a. HDL: __________ TAG: __________ non-HDL: ___________
32. ____ Check blood pressure following standardized procedures while waiting for Cholestech results to print
33. ____ Record results: BP: ____________ _____________ _____________
34. ____ Ask subject about use of wearable technology to monitor physical activity:
    a. Do you wear a device that helps you to monitor your physical activity?_________
    b. If YES, What is the brand/type? ___________
    c. How often do you wear the device?
       1-2 days/wk 3-4 days/wk 5-6 days/wk DAILY

35. ____ Make sure all results are recorded on data collection sheet including height, weight, waist circumference, Bod Pod percentages of pounds and percentages body fat and fat free mass, body mass, blood pressure, and blood glucose and lipid results, and wearable technology questions.
36. ____ Escort the subject back to the EBL
37. ____ Ask subject which flavor oatmeal he/she would prefer (maple brown sugar or cinnamon spice). Remind subject that flavor chosen must be served at next visit as well.
38. ____ Ask subject which beverage he/she would prefer: decaf coffee, decaf tea, or water (all unflavored and no milk or sweetener). Remind subject that beverage chosen must be served at next visit as well.
39. ____ Ask the subject void his or her bladder
40. ____ Make oatmeal breakfast following standardized recipe
41. ____ Prepare requested beverage
42. ____ Record flavor of oatmeal and type of beverage served
43. ____ Set timer for 60 minutes and put it by the UEM computer
44. ____ Ask the subject to complete the initial VAS satiety (before meal) sheet by marking a vertical line (not a circle or an X) in pencil at the appropriate point on VAS sheet. Be sure to record the UEM computer clock time on the VAS sheet
45. ____ While subject is completing the VAS sheet
46. ____ Put the oatmeal on the UEM scale. Start the UEM (steps 7-9 in the UEM Protocol)
47. ____ Ask the participant if they have any questions before starting
48. ____ Escort the subject to the UEM station and have him or her sit down, push in chair, and adjust height to preference

Note: During test breakfasts-

1. Keep lab door closed; put the Test Meal In Progress sign on the outside of the door.

2. Close all doors and ensure that windows fully covered by darkening curtains.

3. Ensure that the subject is comfortable and not distracted during testing.

Say that this is a test breakfast of oatmeal. Water is available for you to drink during the meal, and you may have more if you finish what is in the cup. Please eat and drink as much as you like until you are comfortably full. Keep in mind, once you are finished with your meal, you will not be allowed to have any more to eat or drink for 1 hour. You will be required to stay in the lab for this hour after the first spoonful. I will be keeping track of the meal time for the VAS-Scales, so please ring the bell once right before you take your first spoonful (that is when you are putting your spoon into the meal for the first time to remove pasta to eat), and please ring the bell once when you are finished eating. If you would like more water, please ring the bell 2 quick times and we will bring you another cup.

*Keep in mind, the portion of oatmeal provided is the maximum amount each participant can have. Do not let the participant know this at the beginning of the meal.

<u>When meal begins:</u>

5. ____ When the subject rings the bell the first time (signaling the start of the test meal), record on the data collection sheet the time listed on the computer screen and start the **60-minute timer.**

6. ____ Make sure EBL is dark.

7. ____ Record on the data collection sheet anything that was unusual in the observations table (ex. subject didn't like oatmeal, cleaned the plate, was

feeling sick, didn't follow instructions, moved plate off of scale, used cell phone during meal; test meal preparation; UEM malfunctions).

8. ____ Monitor the LabX light program to ensure continuous UEM recording of the test breakfast.

Upon meal completion:

27. ____ When the subject rings the bell once a second time signaling that he or she is finished eating (signaling the end of the test meal), stop the UEM (step 10 in the UEM Protocol), record on the data collection sheet the time shown on the UEM computer screen, and **start a 20-minute timer.**

28. ____ Note the position of the spoon in the test meal area

29. ____ Escort the subject away from the UEM station. Administer VAS sheet for meal completion; have subject record the wall clock time on the VAS satiety sheet.

30. ____ Print the job report (step 11 in the UEM Protocol); label it with subject ID # and Visit #1. Remove the plate and cup(s) and put them in the kitchen.

31. ____ Inform the subject of the time left that she needs to remain in the lab (from the 60-minute timer).

32. ____ Conduct 24-hour recall #3 and record information on the 24-hour recall sheet. Give special attention to the start and stop times of each meal and record these times on the 24-hour recall sheet.

33. ____ Calculate the 20 minutes post-meal completion time point and record on the data sheet.

34. ____ Administer 20 minutes post meal completion VAS satiety sheet; have subject record the wall clock time on this sheet. If the 24-hour recall has not finished, pause to fill in the VAS sheet and continue the recall once sheet filled out.

35. ____ Administer 7-Day Physical Activity Recall (PAR).

36. ____ Administer the Weight-Related Eating Questionnaire.

37. ____ Administer 60 minutes post meal initiation VAS satiety sheet; have subject record the wall clock time on this sheet.

38. ____ Conduct 3-minute Queens College Step Test following protocol.
39. ____ Record results of step test including pulse rate: ____________________
40. ____ Subject will receive second $100 stipend and receipt; subject to sign TWO copies of receipt; one must be kept by researcher and placed in subject's file.
41. ____ Important: Please take a moment to express sincere thanks for participating in the study. Please inform the subject that their contribution is critical not only to science and the field of nutrition, but to help a graduate student complete her research to meet her goal of graduating ☺. It is okay to really speak openly with the participant about this as completing the study is hard work and we really want them to know how important it is. Thank you!!

After subject leaves the lab:

6. ____ Measure the oatmeal and water/decaf coffee/decaf tea leftovers on the kitchen scale and record the exact weights on the data collection sheet. Make sure the kitchen door is closed during measurements.
7. ____ Complete the calculations for total oatmeal consumed and total drink consumed, and record them on the data collection sheet.
8. ____ Calculate the total time of the meal and record it on the data collection sheet.
9. ____ Add subject's name, date and stipend payment to Excel ELMM Expense Report.
10. ____ File the subject's folder and clean up.

Appendix R (2). Protocol Checklists: PABA Study.

PABA 0 and 8 Visit Day Protocol

Week: ________ # days after Week 0/8:_________

Before subject arrives:

1. ___ Turn on Vmax Encore 29 Indirect Calorimeter at least 20 minutes prior to calibration
2. ___ Perform system calibration

When subject arrives:

16. ___ Greet participant, thank them for returning for PABA visit;
17. ___ Confirm subject's compliance to 10 hour fast and no physical exertion instructions
18. ___ Ask participant to empty their bladder if they haven't already
19. ___ Escort subject to Laboratory 205A and remind him/her that they will be there for 90 minutes
20. ___ Measure height and weight using Weight (and BMI) Assessment Protocol
21. ___ Record weight: __________
22. ___ Ask subject to be seated on laboratory bed with head of bed elevated
23. ___ Encourage subject to adjust so that he/she is comfortable
24. ___ Explain that the first 30 minutes are a resting period, and that we will ask him/her to complete questionnaires while settling in; the second block of time, the next 45 minutes, will be the measurement period
25. ___ Verify that the temperature of the room is comfortable; if not, adjust room temperature and offer blanket if needed
26. ___ Provide a pencil and ask subject to complete the following questionnaires:
    a. Intuitive Eating Scale (IES-2)
    b. Cohen's Perceived Stress Scale
    c. Pittsburgh Sleep Quality Index

27. ___ When subject has completed questionnaires, recline head of bed and explain process of metabolic testing procedure; instruct subject not to read, write, use phone, or sleep for testing period
28. ___ Wait until 30 minute rest period is complete
29. ___ Perform indirect calorimetry measurement
30. ___ When testing is complete, instruct subject that he/she is free to get up
31. ___ Offer subject breakfast/granola bar
32. ___ Schedule and Week and PABA 8 visits if not already scheduled
33. ___ Provide subject with $20 stipend and have him or her sign two copies of receipt

Appendix S. Test Meal Recipe.

Standardized Breakfast: Choice of Maple Brown Sugar or Cinnamon Spice Oatmeal, with choice of cold spring water, hot decaffeinated coffee, or hot decaffeinated tea (no additives for any of the beverage choices).

Ingredients:

3 packages Quaker Maple Brown Sugar Oatmeal OR Cinnamon Spice Oatmeal

16.64 grams butter, salted

340.20 grams milk, whole

11.25 grams Abbott EAS brand whey protein powder, vanilla flavored

Directions:

Pre-weigh and measure all ingredients. Weigh bowl and measuring utensils and record on data sheet. Open each package of oatmeal and empty into pre-weighed bowl. Add butter and pour milk into bowl with oatmeal. Set microwave for 5 minutes and cook on medium-high. When microwave completes 5 minutes, take out bowl, stir, and add protein powder. Stir until mixed together and return to microwave, cooking on medium-high for an additional 30 seconds. When completed, remove bowl from microwave and stir well.

Appendix T. Analyses/additional analyses not included in manuscripts.

Using intent-to-treat analyses, 2X2 repeated measures ANOVAs run to examine between-group differences:

No significance found between experimental (n=37) and control groups (n=35) - (no significant time by group interactions) for:

body weight

systolic blood pressure

diastolic blood pressure

body fat % (Bod Pod-measured)

total grams of meal consumed (UEM-measured)

eating rate (UEM-measured)

PAR-estimated total energy expenditure

waist circumference

fasting glucose

total cholesterol

LDL

non-HDL

Significant differences were seen in time X group interaction in:

HDL (p=.043 - HDL decreased)

TAG (p=0.31 - TAG increased)

There were significant changes over time for both groups in:

body weight (p=.003 - decreased)

systolic blood pressure (p<.001 - decreased)

body fat % (p<.001 - decreased)

Using Completer's analyses, participants removed who started the intervention and dropped out somewhere along the way (experimental group n = 29; control group n = 35):

2X2 RM ANOVAs and found:

No significant differences between experimental and control groups

Over time, both groups lost a significant amount of body fat percentage (p<.001) and increased lean mass percentage (p<.001).

PABA:

No significant differences seen between subset of 20 participants in PABA between experimental and control groups in:

REE (IC-measured)

RQ (IC-measured)

NEW GROUPING: WEIGHT LOSERS VS. WEIGHT STABLE/GAINERS:

In looking at the data in terms of grouping according to weight loss vs. gain, I separated the participants into two groups: Weight Losers (WL) n = 40; and Weight Stable or Gainers (WSG) n = 31:

In running a repeated measures ANOVA looking at UEM-measured ER using Week 0 and Week 8 ER, no significant differences between groups. Also no significance between groups (experimental/control and WL/WSG) for PAR-estimated energy expenditure (Week 8 - Week 0).

Independent samples t-tests run to explore differences between WL and WSG in baseline variables. There were no significant differences between groups at baseline for baseline self-reported eating rate, UEM-measured eating rate, or BMI. I ran Pearson's correlations to examine potential associations between UEM-measured eating rate at Week 0, and body weight change (as defined by Week 8 - Week 0 body weight), and found a weak negative association ($r=-.237$, $p=.047$). There was no significant association between Week 8 UEM-measured eating rate and body weight change.

Pearson's correlation run between eating rate change (UEM Week 8 - UEM Week 0 eating rates) and body weight change, and found a weak/moderate positive association ($r = .338$, $p=.004$). I also ran correlations for eating rate change and waist circumference change, as well as a Spearman's for self-reported eating rate and body weight change, and did not see anything significant.

Tests run to examine differences between groups, in both experimental vs. control groups, and then between weight losers (WL) and weight stable/gainers (WSG) on eating behaviors. I could not use repeated measures ANOVA because the WREQ scores are ordinal. I ran Pearson's correlations between the WREQ score change (Week 8 - Week 0) and body weight change, and found no significant associations between body weight change and change in routine restraint scores, compensatory restraint scores, or emotional eating scores. I did find a weak positive association between body weight change and change in susceptibility to external cues scores ($r=.340$, $p=.003$). In terms of the predictive nature of the Week 0 WREQ scores, I ran Spearman's rho to examine associations between baseline WREQ scores and body weight change because the WREQ scores are an ordinal variable and the body weight change is continuous. There were no significant correlations between body weight change and baseline (Week 0) routine restraint scores, compensatory restraint scores, and emotional eating scores, but there was a weak negative association between body weight change and baseline Week 0 susceptibility to external cues scores ($r=-.320$, $p=.006$).

Independent samples t tests run to look at between group differences (WL vs. WSG) in Week 0 WREQ scores, and found significance between the groups in susceptibility to external cues scores ($p=.009$), but not in the other WREQ construct scores.

Correlations run between eating rate (UEM) change and body fat % change as well as lean mass % change and PAR-estimated energy expenditure change, and found no significant associations. No significant association between PAR-estimated energy expenditure change and WREQ change scores over the 8 weeks, or in WREQ baseline Week 0 scores.

Repeated measures ANOVAs on the moderate category of the PAR (kcals/kg) and found no significant differences between groups (experimental/control AND WL/WSG).

COMPLIANCE DATA:

Means, frequencies, and histograms printed. Correlations run between body weight change and number of days device used, number of meals device used, number of data sheets sent by participant, and number of feedback letters sent to participant - no significant associations were found. Independent samples t-tests examined differences between WL and WSG groups and found no significant associations with self-reported eating rate, body weight change, # days device used, # meals device used, # data sheets sent, # feedback letters sent.

Regarding HDL decrease, it was a significant time by group interaction, of which the p value = .043. In this analysis, HDL decreased more in the control group, so the experimental group with the device had a smaller decrease (Week 0 to Week 8 levels: Experimental = 49.1 -> 48.4; Control = 57.9 -> 53.2)

For the TAG, the significance was actually a significant between groups difference, not a significant time by group interaction. The between groups p value was .031, and so there was a significant difference between control and experimental groups in TAG levels. The values are from Week 0 - Week 8: Experimental = 128.5 -> 134.7; Control = 103.3 -> 108.4).

For the Week 0 WREQ scores for Susceptibility to External Cues between weight losers and weight stable/gainers, the weight losers scores were higher: loser = mean score of 3.29, and stable/gainers = mean score of 2.66. This may suggest that those individuals who were at higher risk of being susceptible to external eating cues had more success with the intervention.

For self-reported eating rate, we do not have Week 0 or Week 8 values, as we only have this information from the baseline questionnaire.

From this baseline measured self-report, SRER was:

Experimental = 3.473

Control = 3.457

WL = 3.597

WSG = 3.290

We do have UEM- measured ER at Week 0 and Week 8.

Experimental Week 0 = 32.23, Week 8 = 28.51

Control Week 0 = 30.64; Week 8 = 31.08

WL Week 0 = 32.69; Week 8 = 28.48

WSG Week 0 = 29.84; Week 8 = 31.45

I did run independent t-tests on SRER between WL and WSG groups, and found no significance ($p=.141$).

The effects sizes (partial eta squared in this analysis) for UEM-measured ER between Week 0 and Week 8 in exp. vs. control groups are:

.011 for time ($p=.382$)

.018 for time by group ($p=.268$)

.000 for between groups ($p=.885$)

Associations explored between Indirect Calorimetry-measured REE and RQ, and body composition and PAR-measured energy expenditure (PAR-EE) in PABA participants. I have found the following significance:

A significant moderate positive correlation between Week 0 REE and change in PAR-estimated energy expenditure (Change = Week 8 minus Week 0) of .436, $p=.043$; increased REE was associated with increased PAR-EE.

A significant weak positive correlation between change in REE and change in body weight change; as body weight change increased, REE increased (r = .459, p=.032)

A significant moderate negative correlation between Week 8 RQ and Week 8 PAR-estimated energy expenditure with r = -.433, and p=.044 (As RQ goes down PAR-EE goes up)

A significant moderate negative association between Week 8 RQ and Week 8 body fat percentage (r=-4.51, p=.035) - as body fat percentage goes down, RQ increases.

Many additional correlations run with no significant associations between:

Week 0 REE with Week 0 BF% and change in BF%
Week 8 REE with Week 8 PAR-EE, BF%, LM%, BW change, and PAR-EE
Week 0 RQ with change in PAR-EE
Week 8 RQ with change in PAR-EE, Week 8 PAR-EE and BF%
Change in RQ and change in PAR-EE
Change in REE with Week 0 BF%, LM%, and PAR-EE

Repeated measures ANOVAs examined at group differences between experimental and control in REE, RQ, body weight, and BF% in these PABA participants with no significance; I ran these RM ANOVAs looking at REE, RQ and LM% with the WL vs. WSG groups and found no significant differences.

Individuals from PABA study with greater PA-EE are burning more fat in the resting state, which aligns with some of the work from MY dissertation.

and:

"as body fat percentage goes down, RQ increases", meaning 'people with more body fat were burning more fat in the resting fasting state'. This aligns with the scientific literature for populations who are relatively homogenous for fitness level; these participants may be burning more endogenous fat.

A significant weak positive correlation between change in REE and change in body weight change; as body weight change increased, REE increased ($r = .459$, $p=.032$)",

= as 'the greater the increase in REE, the more weight was lost'?

Seven pairs of correlations between REE and RQ (using Week 0, Week 8, and change between these weeks as variables) but found no significant associations.

Add analyses run for four ASN submitted abstracts:

Metabolic adaptation abstract:

Used Week 8 REE and Week 8 RQ/fatty acid oxidation results

First WREQ abstract: Used baseline WREQ susceptibility to external cues WREQ and body weight change results and WREQ susceptibility to external cues change and body weight change?

Second WREQ abstract:

Used WL vs. WSG groups – those who lost weight had higher susceptibility to external cues scores at baseline

Eating rate validation results:

Spearman's rho correlation tests examined associations between SRER and ELMM-measured eating rate, which is bite count interval (seconds between bites during meals) – significant moderate negative correlation demonstrating that ELMM is a valid tool to measure eating rate in free-living settings. Spearman's rho to assess associations between SRER and UEM-measured eating rate – no significance. No significance using Pearson's correlations between UEM-measured eating rate and ELMM-measured eating rate.