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## Examining Diet Quality and Sleep Duration in Overweight/Obese Adults in a Weight Loss Intervention

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EXAMINING DIET QUALITY AND SLEEP DURATION IN OVERWEIGHT/OBESE  
ADULTS IN A WEIGHT LOSS INTERVENTION

BY

MEGAN NAQUIN

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS  
FOR THE DEGREE OF MASTER OF SCIENCE  
IN  
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UNIVERSITY OF RHODE ISLAND  
2018

MASTER OF SCIENCE THESIS

OF

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UNIVERSITY OF RHODE ISLAND

2018

## **ABSTRACT**

**Statement of the Problem:** The rate of increased body mass index (BMI) in the adult US population has been alarming within recent decades. Decreased sleep duration has been associated with higher BMI and lower diet quality. BMI and diet quality have been found to be associated with one another as well. The average US adult diet quality score has been indicated as moderately low, which is often associated with higher BMI. In order to confront these alarming rates, weight loss interventions have been researched. A strategy often seen in weight loss success is self-monitoring. Wearable devices, such as the Eat Less Move More (ELMM) device, are able to aid in self-monitoring of physical activity and eating patterns. However, such technology is still emerging, therefore little has been studied regarding the effect such a device may have on weight loss, diet quality, or sleep duration.

**Objective:** As sleep duration (SD) and dietary quality (DQ) have been associated with each other, and with weight in previous research, this study explored SD and DQ and their relationship as outcomes of a novel randomized controlled trial weight loss intervention for overweight/obese adults.

**Methods:** This study is a secondary data analysis of an 8-week intervention with and without the ELMM device for tracking steps, bites, and eating rate on weight loss. Experimental (Ex, n=37) and control (Cx, n=35) groups were mostly female (62.2%, 68.6%) and white (70.3%, 65.7%), and similar in age ( $37\pm 16$ ;  $39\pm 14$  yrs) and BMI ( $31.2\pm 3.5$ ,  $31.5\pm 3.0$ ). Both groups received a workbook at week 0 that introduced nutrition-related topics during the 8 weeks. Outcomes included weight, kcal intake, SD, and DQ. These data were captured week 0 and 8 during in-lab visits and phone

interviews. SD was collected through the 7-Day Physical Activity Recall. Dietary data were collected through three 24-hour dietary recalls at week 0 and 8 (6 recalls total). DQ was calculated using the 2015 HEI scoring algorithm through SAS. Outcomes were examined via paired t-tests and 2-way repeated measures ANOVA; all analyzed as completers analyses.

**Results:** A significant time by group interaction was observed for mean kcal consumed ( $F=4.03$ ,  $p=0.049$ ,  $\text{Eta Sq}=0.061$ ). However, no significant time by group interactions were found for weight loss, SD or DQ. Significant within-group changes were found for total kcals consumed and weight loss from week 0 to 8 for Ex (-300.1kcal/day,  $p=0.013$ ; -1.0g,  $p=0.03$ ), but not for Cx (-19.5kcal/day,  $p=0.82$ ; -0.6kg,  $p=0.07$ ).

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## **PREFACE**

This thesis was written to comply with the University of Rhode Island graduate school Manuscript Thesis Format. This thesis includes one manuscript, “Examining Diet Quality and Sleep Duration in Overweight/Obese Adults in a Weight Loss Intervention” by Megan Naquin, Kathleen Melanson, and Geoffrey Greene. This manuscript is written to align with the publication requirements for the journal of Nutrition and Dietetics.

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**Examining Diet Quality and Sleep Duration in Overweight/Obese Adults In a  
Weight Loss Intervention**

Megan Naquin, Geoffrey Greene, and Kathleen Melanson

Manuscript prepared for submission to the journal of Nutrition and Dietetics.

## **Manuscript Abstract**

**Objective:** As sleep duration (SD) and dietary quality (DQ) have been associated with each other, and with weight in previous research, this study explored SD and DQ and their relationship as outcomes of a novel randomized control trial weight loss intervention for overweight/obese adults.

**Methods:** This study is a secondary data analysis of an 8-week intervention with and without the ELMM device for tracking steps, bites, and eating rate on weight loss. Experimental (Ex, n=37) and control (Cx, n=35) groups were mostly female (62.2%, 68.6%) and white (70.3%, 65.7%), and similar in age ( $37\pm 16$ ;  $39\pm 14$  yrs) and BMI ( $31.2\pm 3.5$ ,  $31.5\pm 3.0$ ). Both groups received a workbook at week 0 that introduced nutrition-related topics during the 8 weeks. Outcomes included weight, kcal intake, SD, and DQ. These data were captured week 0 and 8 during in-lab visits and phone interviews. SD was collected through the 7-Day Physical Activity Recall. Dietary data were collected through three 24-hour dietary recalls at week 0 and 8 (6 recalls total). DQ was calculated using the 2015 HEI scoring algorithm through SAS. Outcomes were examined via paired t-tests and 2-way repeated measures ANOVA; all analyzed as completers analyses.

**Results:** A significant time by group interaction was observed for mean kcal consumed ( $F=4.03$ ,  $p=0.049$ ,  $\text{Eta Sq}=0.061$ ). However, no significant time by group interactions were found for weight loss, SD or DQ. Significant within-group changes were found for total kcals consumed and weight loss from week 0 to 8 for Ex ( $-300.1\text{kcal/day}$ ,  $p=0.013$ ;  $-1.0\text{g}$ ,  $p=0.03$ ), but not for Cx ( $-19.5\text{kcal/day}$ ,  $p=0.82$ ;  $-0.6\text{kg}$ ,  $p=0.07$ ).

**Conclusion:** The potential health benefits posed from self-monitoring, such as significantly lower kcal consumption and weight loss, were further indicated. Over 8 weeks, SD and DQ changed in favorable directions, but slightly and not significantly. Tracking steps, bites, and eating rate did not differentially influence SD and DQ, but their relationship in subjects encourages future research during weight loss.

*Key Words: HEI, Diet Quality, Weight Loss, Self Monitoring, Sleep*

## **Introduction**

In 2011-2012, the average US adult diet quality score was 58.27 out of a possible 100 points, indicating moderately low diet quality<sup>1</sup>. Lower diet quality is positively associated with overweight and obesity<sup>2</sup>. Over the past few decades, there has been a precipitous rise in obesity rates among adults<sup>3</sup>. As these rates have increased, there has been a decrease of 1-2 hours per night in average reported sleep duration<sup>4</sup>, restricted sleep is also associated with lower diet quality and increased BMI<sup>5</sup>. Therefore it is not surprising that over two thirds of the adult population in the US are overweight or obese<sup>6</sup>. In an effort to address this, many types of weight loss interventions, such as caloric restriction and alternate day-fasting<sup>7</sup>, have been researched to reduce the prevalence of these conditions. Factors that are important in weight loss include diet quality and physical activity (PA), as well as energy intake.

A recent 18-month weight loss and weight maintenance intervention<sup>8</sup> (n=197) assessed diet quality scores based on the 2010 Healthy Eating Index (HEI). From 0 to 6 months in the study, HEI scores increased by 20.3 points out of 100 possible points, mean weight reduced by 14.3%, and moderate to vigorous PA increased from 16.9 min/d to 35.9 min/d within the sample. Although this study found that weight loss was associated with increased PA and improved diet quality, these findings need to be replicated in other types of weight loss interventions.

Sleep duration is also related to diet quality score and weight status. Decreased sleep duration has been associated with a higher body mass index (BMI) and lower diet quality<sup>9,10</sup>. Two cross-sectional studies have found a positive correlation between sleep quality and duration, and diet quality<sup>9,11</sup>. However, to the best of our knowledge, the

relationships between sleep duration and diet quality have yet to be investigated during a weight loss intervention. Many studies have explored the relationship between sleep duration and weight gain<sup>12, 13,14</sup> or weight gain prevention<sup>15</sup>. O'Brien and colleagues<sup>16</sup> observed change in sleep duration as an outcome of a weight loss intervention although the intervention did not include sleep. However, O'Brien et al.<sup>16</sup> did not assess dietary quality. Other studies considered sleep duration as a predictor<sup>14,15</sup> of weight loss rather than an outcome of an intervention.

Self-monitoring of PA and eating behaviors have been effective for weight loss<sup>19,20</sup>. Wearable ambulatory bite-counter devices, such as the Eat Less Move More (ELMM) device, also known as the Bite Counter, have the potential to assist in such self-monitoring of activity and eating patterns<sup>21</sup>. The ELMM Study is one of the first studies to test the device for its potential influence on weight loss. The design of the study employs the Social Cognitive Theory, a behavioral theory that is based on the construct of reciprocal determinism<sup>22</sup> in which personal, behavioral, and environmental factors all influence and are influenced by one another.

The ELMM Study collected data on diet quality, sleep duration, PA, and BMI in overweight and obese adults within Rhode Island. The purpose of the current study is to observe dietary quality and sleep duration as outcomes of a self-monitoring and workbook-based weight loss intervention. The primary hypothesis is that the diet quality of the subjects with the wearable device would improve more than in the participants who did not receive the device. The secondary hypothesis is that sleep duration of the subjects in the experimental group would improve more than in the participants who did not

receive the device. We investigated change in energy intake and weight between the two groups, as well as relationships of diet quality, sleep duration, and PA.

## **Methods**

### *Study Design*

This is a secondary data analysis using data from the ELMM Study, an 8-week randomized controlled trial. Subjects within this study were recruited with fliers, mass emails, and classroom announcements at University of Rhode Island, with the overlying goal of recruiting students and faculty. In order to participate, potential participants were required to meet the following criteria: non-smoking, 18-60 years of age, not currently pregnant or lactating, BMI between 27-37 kg/m<sup>2</sup>, no history of metabolic disease or documented eating disorders, and not currently taking medications that may affect appetite. Seventy-seven participants were recruited, 64 retained.

This project required three individual lab visits (baseline, Week 0, and Week 8) for each participant as well as a phone screening to determine eligibility. At the baseline visit informed consent (Appendix B) was obtained, height and weight measured to confirm BMI, and portion size booklets were provided as reference for future unannounced 24-hour dietary recalls. Two multiple pass 24-hour dietary recalls were collected by phone before each visit. The Week 0 visit required a 10-hour fast prior to visit commencement, which included another set of anthropometric measurements and a test breakfast that was served in lab on a universal eating monitor. After the breakfast, a 24-hour dietary recall and a 7-Day Physical Activity Recall (7-Day PAR) were conducted in-lab. These measurements were taken pre- and post-study.



Randomization of participants occurred after inclusion criteria was met and based on the random selection of the previous participant (the first was determined by coin toss). Participants in both groups were then introduced to the intervention workbook. This workbook was created at the URI and has yet been published; it focuses on reducing eating rate and increasing PA, as well as reducing the energy density of food and reducing liquid kcal consumption. The experimental group was provided the ELMM in addition to the workbook and shown how to use the device. The Week 8 visit included the same measurements and tests as Week 0, and the experimental group returned their device. Subjects were progressively compensated for their time within the study, \$160 total.

### *Instruments*

#### Anthropometric and Demographic Data

Anthropometric measures were conducted according to standard procedures<sup>23</sup>. Height and weight were both measured in duplicate and averaged. Height was measured using a digital wall-mounted stadiometer (SECA 240, Hamburg, Germany) and rounded to 0.1 cm. Weight was measured in duplicate using a digital scale (SECA 700, Hamburg, Germany) and rounded to 0.1 kg. Trained team members collected these measurements for each participant during their Week 0 and Week 8 visits. BMI, calculated as  $\text{kg/m}^2$  using height and weight, is an indicator of health and adiposity<sup>24</sup>, and is used descriptively. Weight, measured in kg, was used to determine weight change pre- and post-study. Data on sex, race, ethnicity, and age were collected during the phone-screening process, conducted by a trained team member.

#### Diet Quality Measures

Two multiple pass 24-hour dietary recalls (Appendix D) were administered by a trained member of the research team over the phone prior to the Week 0 and 8 visits. Additionally, one 24-hour dietary recall was conducted in-person during each visit (6 recalls total). One recall reflects weekend intake and two recalls reflect weekday intakes. This trained team member recorded brand names, portion sizes, and quantities of foods per participant recollection with the assistance of the portion size estimator handbook (Fred Hutchinson Research Center, Seattle, WA, 2015) provided at the baseline visit. These recalls were then analyzed using the validated<sup>25</sup> Automated Self-Administered 24-Hour Dietary Recall (ASA24)<sup>26</sup> in order to measure energy intake and calculate cups or weighted ounces per HEI scoring category.

These data were used to calculate the HEI score in order to indicate diet quality pre- and post-intervention. The 2015 HEI utilizes a one to 100 score to indicate diet quality; a higher number indicates a higher quality diet. HEI scores are calculated based on 13 components, each ranging from 0 to 20 points: total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids (polyunsaturated fatty acid + monounsaturated fatty acid-to-saturated fatty acid ratio), refined grains, sodium, added sugars, and saturated fat. Each recall conducted within the ELMM Study was given an HEI score and three-day averages of the HEI scores were used to calculate overall participant diet quality pre- and post-intervention. A change in this score from pre- to post-intervention indicates an increase or decrease in diet quality. The scores were calculated through the 2015 HEI algorithm within SAS (SAS Institute Inc. version 9.4, Cary, NC, 2013).

#### PA and Sleep Duration Measures

During the Week 0 and Week 8 visits, participants were interviewed about the frequency, duration, type, and intensity of PA within the past 7-day time period. This interview used a standard protocol with the validated 7-Day PAR<sup>27</sup> (Appendix C). PA was measured in minutes per week, as averaged at each Week 0 and Week 8 visits. The reported 7-day PA categories of “moderate”, “hard”, and “very hard” activities were summed to produce a moderate-to-vigorous PA measure per subject, per week. These data were analyzed as a continuous variable. The 7-Day PAR also measures the approximate number of hours of sleep they received each night during that 7-day time period; this value was used for sleep duration. In order to obtain average hours of sleep, sleep duration means were calculated at Week 0 and 8. Analyses were conducted with sleep measured as a continuous variable.

#### *Statistical Analysis*

The statistical package SPSS (IBM version 24.0 SPSS Inc, Chicago, IL, 2016) was used for all analyses. All data were normally distributed. Outliers were identified but were not excluded as there were no significant differences in data when tests were repeated. To assess the time by group interaction of sleep duration and dietary quality, 2-way repeated measure ANOVA were conducted. Further 2-way repeated measures ANOVA were conducted on mean weight, PA, and average kcal consumed. Baseline independent t-tests were conducted on all outcomes of interest. Paired t-tests were run on variables for within group differences. Pearson’s correlations were run with SD and HEI scores for 1) mean weight, 2) moderate-to-vigorous PA, 3) average kcal consumed, 4) HEI component scores. Acceptance of significance was identified as  $p < 0.05$ .

## Results

### *Subject Characteristics*

Seventy-two subjects, ages 18-60 ( $38 \pm 15$  years), were randomly assigned to the intervention (n=37) or control (n=35) groups, 64 subjects were retained (17% attrition). As shown in Table 1, subjects were mostly non-Hispanic (75%) white (68%) women (65%), all of which were at least overweight ( $31.3 \pm 3.2 \text{ kg/m}^2$ ). Independent t-tests revealed no significant baseline differences between groups. Results described are completers analyses (n=64).

### *Diet Quality and Sleep Duration*

As shown in Table 2, the hypothesis that dietary quality will increase more in the experimental group than the control from pre- to post-intervention was not supported. The 2-way repeated measures ANOVA demonstrated no significant time by group interactions for dietary quality ( $F=0.004$ ,  $p=0.765$ ,  $\text{Eta Sq}<0.001$ ). Sleep duration predictions were also not supported. The 2-way repeated measures ANOVA demonstrated no significant time by group interactions for sleep duration ( $F=0.09$ ,  $p=0.947$ ,  $\text{Eta Sq}<0.001$ ). While neither of these variables yielded significant time by group interactions, sleep duration (Experimental (Ex):  $7.5 \pm 1.0$ ,  $7.7 \pm 0.9$ ; Control (Cx):  $7.6 \pm 0.9$ ,  $7.7 \pm 0.9$  hours) and dietary quality (Ex:  $54.6 \pm 12.4$ ;  $56.5 \pm 14.8$ ; Cx  $54.4 \pm 7.9$ ;  $56.1 \pm 10.5$ ) trended, in both groups, in a positive direction. No within group paired t-tests (Table 2) or between group independent t-tests demonstrated significance for dietary quality or sleep duration when conducted. When conducted on the whole sample, Pearson's Correlations (Table 3) revealed no significant association between change of sleep duration and dietary quality from pre- to post-intervention ( $r=-0.172$ ,  $p=0.185$ ).

### *HEI Components*

Further paired t-tests were run for all described HEI components: total fruits, whole fruits, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids, refined grains, sodium, added sugars, and saturated fats. Significance determined for the variables were based on a Bonferroni correction due to multiple comparisons. Within Table 4, paired t-tests were run on the whole sample for each component and yielded significance for saturated fat ( $p=0.005$ ). Within group time interactions were assessed as well, and found significance for saturated fat within the experimental group ( $p=0.009$ ).

### *Energy Intake, Weight Loss, and PA*

Two-way repeated measures ANOVA found a significant time by group interaction with average kcal consumed ( $F=4.0$ ,  $p=0.049$ ,  $\text{Eta Sq}=0.061$ ) seen in Figure 1, but in no other outcomes including weight loss or PA. It is important to note that baseline average kcal consumption did not significantly vary ( $p=0.285$ ). Paired t-tests demonstrated within experimental group significance for mean weight loss ( $p=0.030$ ) and average kcal consumed ( $p=0.013$ ), but not for PA ( $p=0.053$ ). The control group did not demonstrate within-group significance for those variables.

### **Discussion**

In this 8-week workbook-based weight loss intervention, total dietary quality score and sleep duration did not change within or between groups, nor were they associated with one another. It is likely that significance was not seen for the primary and secondary hypotheses due to high variability in both dietary quality ( $2.0\pm 9.9$ ) and sleep duration ( $0.1\pm 0.9$  hours/day). Total HEI scores and sleep duration still increased in both

groups. The lack of effect is consistent with the short-term Salley<sup>28</sup> et al. study, which had stated that the ELMM (then called Bite Counter) alone has no impact on dietary quality.

The lack of relationship between dietary quality and sleep duration is similar to other studies. Mossavar-Rahmani et al.<sup>29</sup>, using a cross-sectional probability sample and self-report data from a community-based cohort study of Hispanics/Latinos in the US, found no relation between diet quality (as assessed by the 2010 Alternative-HEI) and sleep duration. Similar to the results of this study in terms of sleep duration (as assessed by the Pittsburgh Sleep Quality Index), a study in overweight and obese women<sup>16</sup> also found no within group significance. The intervention consisted of weekly 1-hour group meetings that provided a caloric-restriction recommendation, a fat gram goal, PA activity goals for a progressive increase of PA to 200min/week, sample meal plans and vouchers for meal replacement products, and were taught behavioral skills targeting eating habits and PA levels. However, the control group was given four 1-hour group sessions in which information regarding weight loss, PA, and healthy eating habits was provided. O'Brien et al. did not find significance with sleep as a predictor of weight loss or a significant difference with the experimental group with sleep. Unlike O'Brien et al., the present secondary data analysis did not limit participant gender and included influencers of dietary quality within the workbook provided to both groups, which has been associated with sleep duration<sup>9</sup>. One reason by which significance was not found in the O'Brien et al. study may be due to lack of a sleep component within the intervention, this may have also been the case in the present study as well. However, the subjects within this study had little or no room for improvement in regard to their sleep duration at

baseline (Ex:  $7.5 \pm 1.0$ ; Cx:  $7.6 \pm 0.9$  hours/day); therefore, there likely would not have been a significant improvement in sleep even if the intervention had a sleep adequacy component incorporated.

While the hypotheses have been rejected, various aspects of the intervention, specifically the nutrition workbook, yielded success as evidenced by weight loss seen in both groups (Ex:  $-1.0 \pm 2.4$ ; Cx:  $-0.6 \pm 1.8$ kg). The one between group difference found was for change in mean kcal intake. Experimental group subjects reduced kcal more than the control group. Thus, it can be suggested that participants with the ELMM, through its bite-counting algorithm, were able to more closely monitor their energy intake or at least be more aware of their intake than the control group. Success was also found in the sample through improved HEI component scores, specifically reduced saturated fat consumption (+0.94 component score, pre- to post-intervention), indicated by a higher component score, as well as increased fatty acid score (+0.82 component score, pre- to post-intervention).

It can be suggested that these improved food categories and scores may have encouraged weight loss success and decreased caloric intake in the sample through their satiating effects. Throughout the literature<sup>7,30</sup>, reducing kcal has been correlated with weight loss and employed in many weight loss interventions. Lower kcal consumption through increasing nutrient dense foods, as seen within this study, and weight loss have been connected to satiety<sup>31</sup>, indicated by lower serum levels of ghrelin, and higher peptide YY, and glucagon-like peptide-1<sup>32</sup>. Dietary factors that have been found to influence satiety biomarkers are fat<sup>33</sup>, protein<sup>34</sup>, and fiber<sup>35</sup>. Recently, the type of fat consumed has been explored further in relation to satiety. Increasing monounsaturated

fatty acids (MUFAs) and polyunsaturated fatty acids (PUFAs), both found in fatty fish, nuts, and olive oil, has been linked with higher satiety<sup>32,36</sup>. The suggested mechanism that drives this is the potential suppressive effect on ghrelin that MUFAs and PUFAs have compared to saturated fat. This mechanism may act as an alternative reason why there was significant weight loss success in the experimental group as opposed to simply assuming the ELMM device yielded this success.

While this study has taken some initial steps in progressing the literature in weight loss, there are some limitations to consider. First, the self-reported data from participants, namely the dietary and PA data, may not be entirely accurate. It has been identified within the literature<sup>37,38</sup> that overweight and obese samples may underreport dietary data more than samples with a healthy BMI. Additionally, while sleep duration was a secondary outcome of this analysis, it was not incorporated in the intervention like aspects of dietary quality and PA were. Therefore, if research is to continue regarding sleep and weight loss, it may be necessary to include sleep within the intervention. However, our purpose was to determine if sleep would change as a result of the intervention. There are also many environmental and biological factors that effect sleep that were unable to be controlled for this study such as depression<sup>39</sup>, anxiety<sup>40</sup>, stress<sup>41</sup>, sleep medications, and obstructive sleep apnea<sup>42</sup>. Further, the 7-Day PAR is not validated for sleep duration. The 7-Day PAR is intended for estimating total energy expenditure; sleep duration is collected with this tool for the purpose of calculating resting metabolic rate to aid in approximating total energy expenditure. While there are limitations, this study has considerable strengths.



This analysis is the first of its kind to observe dietary quality within the context of a weight loss study using the ELMM. Prior literature<sup>43,44</sup> regarding this device collected dietary data for the purpose of exploring energy intake, but did not dietary quality. As a result, this study has produced novel findings unique to the ELMM being used within a weight loss intervention. While this is not the first study<sup>43,44</sup> to include a nutrition intervention with the ELMM for weight loss outcomes, it is the first study to utilize a workbook-based intervention. Further, approximately six dietary recalls were collected for each participant who completed the study, this is substantially more dietary data than prior studies<sup>29,45</sup>. Additionally, the randomized controlled trial design that this study models is the gold standard for research, and there was high homogeneity amongst the two groups.

### **Future Implications and Conclusions**

While this intervention did not yield a significant effect on either total dietary quality or sleep duration, these aspects of health should continue to be explored within weight loss interventions. The workbook created for this study can be further improved by incorporating a sleep component in order for change in sleep to be better assessed with weight loss. Additionally, the eating rate portion of the workbook can be expanded to include more information on satiety cues and information on the foods that promote satiety. The potential health benefits posed from self-monitoring, such as significantly lower kcal consumption and weight loss, are further indicated within this study. These findings within the HEI component scores add to the budding research regarding satiety and types of fat.

Over 8 weeks, sleep duration and diet quality changed in favorable directions, but slightly and not significantly. Tracking steps, bites, and eating rate did not differentially influence sleep duration and dietary quality, but their relationship in the literature encourages future research during weight loss.

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## Tables and Figures

Table 1. Mean Demographic Values by Group at Baseline – Whole Sample			
Variable Mean ( $\pm$ SD)	Experimental (n=37)	Control (n=35)	p
Age (years)	37 (16.0)	39 (14.3)	0.511
BMI (kg/m <sup>2</sup> )	31.2 (3.5)	31.5 (3.0)	0.687
Weight (kg)	88.9 (14.2)	89.6 (14.6)	0.851
Gender n (%)			0.574
Female	23 (62.2)	24 (68.6)	
Male	14 (37.8)	11 (31.4)	
Ethnic Background n (%)			0.154
Hispanic	1 (2.7)	4 (11.4)	
Non-Hispanic	29 (78.4)	25 (71.4)	
No Answer	7 (18.9)	6 (17.1)	
Race n (%)			0.926
American Indian	0 (0.0)	1 (2.9)	
Asian	6 (16.2)	3 (8.6)	
Black	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)	
SD – standard deviation, BMI – Body Mass Index, kg/m <sup>2</sup> – kilograms over meters squared; *p<0.05, **p<0.01; Intent to Treat Analysis; Independent Samples T-Test			

Var	Group	Pre	Post	Change	Time x Group		Time	
		Mean (± SD)	Mean (± SD)	Mean (± SD)	F	Eta Sq	F	Eta Sq
HEI	Ex n=29	54.6 (12.4)	56.5 (14.8)	1.9 (10.8)	0.004	0.000	2.442	0.038
	Cx n=35	54.4 (7.9)	56.1 (10.5)	2.0 (9.4)				
Sleep (hr/d)	Ex n=29	7.5 (1.0)	7.7 (0.9)	0.2 (1.1)	0.090	0.002	1.352	0.022
	Cx n=35	7.6 (0.9)	7.7 (0.9)	0.1 (0.7)				
Weight (kg)	Ex n=29	89.1 (15.3)	88.1 (14.6) <sup>a</sup>	-1.0 (2.4)	0.707	0.011	**9.080	0.128
	Cx n=35	89.6 (14.6)	89.0 (14.7)	-0.6 (1.8)				
Avg EI (kcal/d)	Ex n=29	2069 (577.6)	1769.3 (624.0) <sup>a</sup>	-300.1 (610.3)	*4.029	0.061	**5.223	0.078
	Cx n=35	1874.3 (585.9)	1854.0 (529.3)	-19.5 (508.7)				
MVPA (min/ wk)	Ex n=29	241.2 (248.7)	279.0 (250.6)	37.88 (327.6)	0.019	0.000	1.129	0.018
	Cx n=35	299.5 (226.9)	348.4 (262.4)	48.9 (323.0)				

Var – variable, Sleep – sleep duration, hr – hour, d – day, MVPA – moderate-to-vigorous physical activity, min – minutes, wk – week, Avg EI – average energy intake, HEI – dietary quality, Ex – Experimental, Cx – Control; Completers Analysis; 2-way repeated measures ANOVA ; \*p<0.05, \*\*p<0.01; Within Group Paired T-Test Significance<sup>a</sup>; <sup>a</sup>p<0.05

Variable n=64	Mean Change (± SD)	Correlation with HEI r, p	Correlation with SD r, p
HEI	2.0 (9.9)		-0.172, 0.185
Sleep (hr/d)	0.1 (0.9)	-0.172, 0.185	
Weight (kg)	-0.8 (2.1)	-0.143, 0.258	0.191, 0.140
Avg EI (kcal/d)	-146.6 (570.1)	-0.206, 0.103	0.065, 0.621
MVPA (min/wk)	43.9 (322.5)	-0.186, 0.14	-0.102, 0.434

Cm – centimeters, %BF – percent body fat measured by BodPod, HEI – dietary quality; \*p<0.05, \*\*p<0.01; Completers Analysis; Pearson's Correlations

Table 4. Sample and Within Group HEI Component Scores, Pre- to Post-Intervention – Completers						
<b>Variable (Possible Score)</b>	<b>Mean Score Week 0 (± SD)</b>	<b>Mean Score Week 8 (± SD)</b>	<b>Mean Change (± SD) n=64</b>	<b>Ex Mean Change (± SD) n=29</b>	<b>Cx Mean Change (± SD) n=35</b>	<b>t</b>
Total Fruits (5)	2.0 (1.4)	2.2 (1.6)	0.2 (1.5)	0.4 (1.3)	0.0 (1.6)	0.896
Whole Fruits (5)	2.1 (1.8)	2.2 (1.8)	0.1 (1.8)	0.2 (1.8)	0.0 (1.8)	0.488
Total Vegetables (5)	3.4 (1.3)	3.4 (1.3)	0.0 (1.3)	-0.3 (1.4)	0.3 (1.2)	0.112
Greens and Beans (5)	2.6 (1.6)	2.5 (1.8)	-0.1 (1.7)	-0.6 (1.6)	0.4 (1.7)	-0.391
Whole Grains (10)	3.2 (2.3)	3.3 (2.9)	0.1 (2.9)	0.5 (2.9)	-0.2 (3.0)	0.362
Dairy (10)	5.4 (2.4)	5.5 (2.7)	0.1 (2.8)	0.0 (2.7)	0.2 (2.9)	0.322
Total Protein Foods (5)	4.4 (0.7)	4.6 (0.7)	0.2 (0.93)	0.2 (1.0)	0.2 (0.8)	1.567
Seafood and Plant Proteins (5)	2.9 (1.6)	2.9 (1.6)	0.0 (1.7)	-0.5 (1.8)	0.3 (1.6)	-0.137
Fatty Acids (10)	5.3 (2.5)	6.2 (2.5)	0.8 (3.0)	1.2 (2.9)	0.5 (3.1)	2.204
Refined Grains (10)	5.7 (2.8)	5.9 (3.0)	0.3 (2.9)	0.4 (2.8)	0.2 (3.0)	0.696
Sodium (10)	3.7 (2.3)	3.0 (2.4)	-0.6 (2.3)	-0.6 (2.2)	-0.7 (2.4)	-2.207
Added Sugars (10)	8.1 (1.8)	8.9 (2.0)	0.0 (2.1)	-0.4 (2.2)	0.3 (2.1)	-0.060
Saturated Fats (10)	5.8 (2.7)	6.7 (2.4)	*0.9 (2.6)	*1.4 (2.8)	0.5 (2.5)	2.876
Ex – experimental group, Cx – control group; degrees of freedom were 63 for all components; Bonferroni Correction *p<0.01; Completers Analysis; Paired T-Test						

Figure 1: Average Kcal Consumed Pre to Post-Intervention – Completers

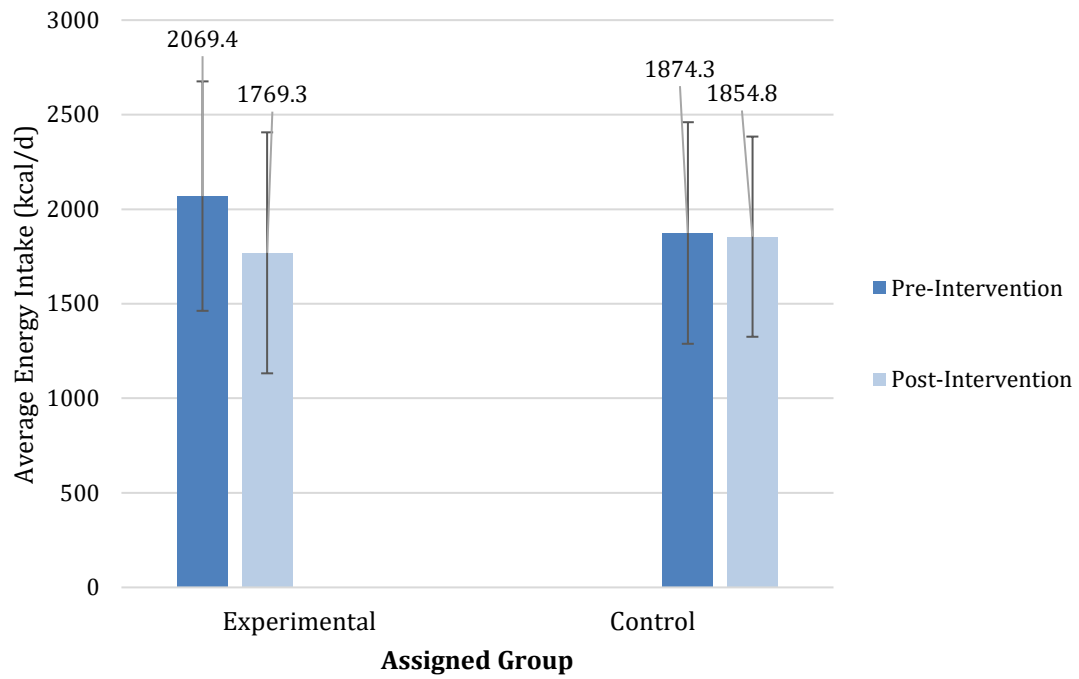


Figure 1. Mean kcal intake at pre- and post-intervention, both groups. Significance found time by group ( $p=0.049$ ). No significant baseline differences between groups kcal means ( $p=0.186$ ).

## APPENDIX A: Review of the Literature

### *Introduction*

In 2011-2012, the average US adult diet quality score, as assessed by the 2010 Healthy Eating Index (HEI), was 58.27 out of a possible 100 points, indicating moderately low diet quality<sup>1</sup>. Lower diet quality is positively associated with overweight and obesity<sup>2</sup>, therefore it is not surprising that over two thirds of the adult population in the US are overweight or obese<sup>6</sup>. Over the past few decades, there has been a precipitous rise in obesity rates among adults<sup>3</sup>. As these rates have increased, there has been a decrease of 1-2 hours per night in average reported sleep duration<sup>4</sup>. In order to combat this ever-increasing BMI trend in the US, many behavioral and dietary weight loss interventions have been employed and systematically reviewed<sup>46-48</sup>. Three components of health that are commonly found within the research regarding weight loss are: diet quality, sleep duration, and PA. However, the relationships between sleep duration and diet quality have yet to be investigated within a weight loss intervention.

During weight loss interventions, self-monitoring of PA and eating behaviors have shown efficacy<sup>19,20</sup>. Wearable ambulatory bite-counter devices, such as the Eat Less Move More (ELMM) device, have the potential to assist in self-monitoring activity and eating patterns, which are important components of weight loss interventions<sup>21</sup>. The purpose of this literature review is explore BMI, diet quality, PA, sleep duration, and self-monitoring as a means of successful weight loss.

### *BMI and Weight Loss*

Overweight and obesity, as indicated by a higher BMI, pose many threats to health such as hypertension, dyslipidemia, and diabetes<sup>6</sup>. Because over two thirds of the

US adult population is overweight or obese, interventions are needed to reduce the prevalence of these conditions. Weight loss interventions, from simple caloric-restriction to alternate day-fasting, have been explored to curb these continued trends in BMI<sup>7</sup>. Weight loss can only be achieved through negative energy balance, in which kilocalories (kcal) consumed are less than energy expended. Two factors that are important in achieving this negative energy balance are diet quality and PA.

High diet quality scores and adequate PA have consistently been correlated with healthier BMI. Within an observational study, Leong et al. indicate that high diet quality is associated with a healthier BMI<sup>49</sup>. Another study<sup>50</sup> that investigated PA and aspects of diet quality, PA was categorized by aerobic exercise, strength training, and education classes and was quantified by number of days in a 7-day period each category was practiced. Huang et al. found that overweight college students engaged in little PA (as defined by <30 minutes per day, for most days in the week), ate fewer fruits and vegetables, and had less fiber in their diet when compared to their healthy-weight peers. These data indicate indirect associations between healthier BMI and both diet quality and PA. Further, improved diet quality and PA have both been correlated with negative energy balance.

A recent 18-month weight loss and weight maintenance intervention<sup>8</sup> assessed diet quality scores based on the 2010 Healthy Eating Index (HEI). The study sample was comprised of overweight or obese, middle-aged men (n=65) and women (n=132). Within the weight loss intervention meetings were held weekly (0-6 months) and then tapered during weight maintenance (7-18 months), sessions focused on reviewing self-reported data; a lesson regarding nutrition, PA, or lifestyle modifications; and group discussion.

The diet intervention for weight loss was to reduce total kcal consumption to 1200-1500kcal/d; and included eating 5 cups of vegetables and fruits, consuming 2 pre-packaged entrees provided, and drinking 3 premade shakes each day. During weight maintenance, participants were instructed to consume kcal suggested for weight maintenance as determined by the Mifflin-St. Jeor equation and to continue consuming 5 cups of vegetables and fruits daily. Finally, participants were asked to complete 300 min/week of moderate to vigorous PA through all 18 months and were provided an accelerometer to self-monitor steps. From baseline to month 6 in the study, HEI scores increased by 20.3 points out of 100 possible points, mean weight reduced by 14.3%, and moderate to vigorous PA increased from 16.9 min/d to 35.9 min/d within the sample. These data indicate that weight loss may be achieved through prepackaged low-energy foods leading to a higher quality diet and increasing PA.

A different, but similarly structured, study<sup>45</sup> investigated how diet quality and weight loss might correlate after a weight loss intervention. The study sample was comprised of rural breast cancer survivors aged 75 years or younger, BMI 27-45kg/m<sup>2</sup>, whom lost  $\geq 5\%$  of baseline weight from a weight loss intervention initiated six months prior. For inclusion in the weight maintenance and diet quality analysis, two diet recalls from both baseline and six months were needed (n=180). The intervention in the initial 6-month study was phone-based, in which participants were in groups of 10-15 and asked to follow a 1200-1500kcal/d diet of pre-packaged meals, and follow guidelines based on MyPlate recommendations that encourage higher diet quality – much like Ptomey et al. study<sup>8</sup>. Other aspects of this intervention include the gradual inclusion of 225 min/week of moderate to vigorous PA as well as self-monitoring of weight, dietary intake, steps,



and daily exercise. Diet quality, measured by the 2010 HEI based on 24-hour dietary recalls, increased over the 6-month period from  $51.93 \pm 11.19$  to  $64.04 \pm 10.52$  ( $p=0.001$ ) as mean weight decreased by 13.2% from baseline. These results indicate that change in diet quality from baseline may be correlated with weight loss, however PA was not studied as a primary outcome in this study. As the association of increased PA and diet quality have been seen with weight loss, it is increasingly important to view these variables within other weight loss interventions.

### *Diet Quality*

Diet quality, within the US, is a measure used to indicate if an individual's diet aligns with the Dietary Guidelines for Americans<sup>2</sup> (DGAs). Diet quality has been found to differ by age, sex, race/ethnicity, income level, and education level. An analysis of NHANES data ( $n=8272$ ), utilizing the 2005 HEI to measure diet quality, found that children and older adults scored higher on dietary quality than younger and middle-aged adults and women scored better than men<sup>51</sup>. Hiza et al. also found that Hispanics scored better than blacks and whites and that the diet quality of adults, not children, normally improved with socioeconomic status, except for sodium<sup>51</sup>. Therefore, within studies including diet quality as an outcome, it is important to control for factors such as age, sex, race/ethnicity, and income level. Furthermore, it is important to ensure efficacy of measures through selecting a validated diet quality index.

Globally, there are many validated measures that exist to measure diet quality. Diet quality measures can vary greatly based upon the nutrition guidelines set by each country. There are numerous measures that are appropriate for research within the US. The majority of these indices of diet quality evaluate food choices and behaviors that are

compatible with a healthy lifestyle<sup>52</sup>. Measures of diet quality, including the HEI, the Alternative Healthy Eating Index (AHEI), Diet Quality Index (DQI), Recommended Food Score (RFS), and alternate Mediterranean Diet Index (aMDI), are highly correlated<sup>52</sup>. Four of the more common diet quality indices are the HEI, AHEI, Alternate Mediterranean Diet Score (aMED), and the Dietary Approaches to Stop Hypertension (DASH) score<sup>53</sup>. Diet quality indices generally include energy adjusted nutrient intake, quantity of food groups such as fruits and vegetables, and are scored on a fixed scale in which a higher score indicates a higher quality diet. At this time, there is no universally accepted measure of diet quality.

The current HEI, based on the 2015-2020 DGAs, has recently been developed. The original HEI was created in 1995 by the United States Department of Agriculture's Center for Nutrition Policy and Promotion. Since the initial release, updates are made every 10 years based on the revisions made to the DGAs. The validated 2010 HEI<sup>54</sup> utilizes a score out of 100 to indicate diet quality; a higher score indicates a higher quality diet. HEI scores are calculated based on 12 components, each ranging from 0 to 20 points: total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids (polyunsaturated fatty acid + monounsaturated fatty acid-to-saturated fatty acid ratio), refined grains, sodium, and empty calories from solid fats, alcoholic beverages (beer, wine, and distilled spirits), and added sugars<sup>54</sup>. The 2010 HEI is the most inclusive index of the four common indices (HEI, AHEI, aMED, and DASH) as it has 12 categories for foods and beverages, the most categories of the four, providing a general picture of diet quality. Since April 2017, there has been an updated 2015 HEI released to the public, the update removed the

general empty calorie category, and replaced it with two categories: saturated fat and added sugars. Validation and reliability results of the 2015 HEI scoring standards are yet to be published. While the HEI acts as a general measure of diet quality, the AHEI was designed to capture dietary factors linked with risk of cardiovascular diseases (CVD) development<sup>55</sup>.

The AHEI scores diet quality out of 110 and 11 components. The components included in this index are: whole grains, vegetables (potatoes excluded), fruits, nuts/legumes, trans-fats, eicosapentaenoic acid + docosahexaenoic acid ( $\omega$ -3 fatty acids), polyunsaturated fatty acids, alcohol, red and processed meats, sugar-sweetened beverages and fruit juices, and sodium<sup>56</sup>. Most categories for HEI and AHEI are similar; the primary differences lie in the specific categories for assessing CVD risk (ie. specific fat categories and red/processed meat consumption) found in the AHEI. Unlike the HEI and AHEI, the aMED and DASH both have fewer categories and a lower point scale. Regardless of number or type of components, a higher score on each of these four common diet quality indices indicate lower risk of all cause-mortality<sup>53</sup>. Diet quality score often correlates with BMI and mortality.

Lower diet quality score is associated with obesity and is independently associated with total mortality and risk of mortality from CVD, cancer, and inflammatory-related disease (such as infection, benign tumors, metabolic disorders, etc.)<sup>2,57</sup>. The components of HEI, have been associated with reduced risk of chronic disease development, such as CVD and cancers, which may decrease total mortality risk<sup>58,59</sup>. However, high scores on both AHEI and HEI are associated with lower risk of total mortality<sup>58</sup>. A recent meta-analysis of observational studies was unable to determine

if AHEI or HEI is better at predicting reduced mortality because there are only slight differences in categorization of foods<sup>56</sup>. Instead, 2010 AHEI has separate categories for trans fats, sugar sweetened beverages/fruit juice, and alcohol<sup>54</sup>. In order to calculate diet quality, however, intake of food must be collected.

There are a few different tools that are commonly used to collect dietary data: Food Frequency Questionnaires (FFQs), 24-Hour Dietary Recalls, and Food Diaries or Logs. Each of these tools can be completed without guidance; however, the FFQ and 24-Hour Dietary Recalls are practiced with guidance depending on the protocol for a study whereas Food Logs are typically done progressively per subject. FFQs provide a list of foods within different categories or food groups and ask how frequently each item is consumed, whereas recalls or logs require time of consumption, amount consumed, and food/beverage item specifics such as brand or cooking method. While each of the collection methods obtain valid dietary data from subjects, recalls and logs are preferred due to more detailed day-to-day intakes from participants rather than a general scope of a subject's intake. The validated<sup>60</sup> 24-hour dietary recall is revered as the gold-standard measure of estimating energy intake and diet quality<sup>61</sup>. However, there are some marked limitations regarding this tool, one of which lies in the fact that this is a self-report tool relying on accurate recall on quantity and quality of food and beverage items being consumed. Participants that self-report are fairly erroneous in their recollection of food intake. Underreporting of quantity of food is an issue found more commonly among women and overweight/obese individuals<sup>62</sup>, leading 24-hour dietary recalls to be a slightly inaccurate depiction of a participant's daily intake. While this measure of food intake does have limitations, the flexibility of this tool is optimal for many interventions.

Once data are collected, the next course of action, within the context of dietary quality, is to score the data based on the scoring algorithm chosen (2015 HEI, in this case). As discussed previously, there are different scoring categories within the 2015 HEI, this requires dietary data to be entered into a validated dietary software/database to produce cup by cup amounts per category based on recorded data. Many studies<sup>45</sup> have utilized Nutrition Data System for Research (NDSR) for this task. However, within this secondary data analysis, the Automated Self-Administered 24-Hour Dietary Recall<sup>26</sup> (ASA24) database was used. ASA24 is typically used as a self-administered recall tool<sup>63</sup>, and has been validated as such<sup>25</sup>, but studies can utilize this database for retroactive data entry in order to get the desired outputs for the scoring algorithm due to its accessibility and reliability. Once the outputs are obtained, they are run through the HEI algorithm, typically through the statistical software, SAS.

### *Physical Activity*

As described previously, PA is an important variable within weight loss interventions. PA is categorized by intensity of activity, from moderate to vigorous intensity<sup>64</sup>. Intensity refers to the level of effort required by an individual to do an activity. Intensity level for any activity varies by person; in order for an activity to be classified as moderate, an individual must be able to talk but not be able to sing while doing an exercise, whereas vigorous intensity PA requires the individual to be unable to speak without stopping for breaths between words. Adequate PA for good health is 150 minutes of moderate intensity or 75 minutes of vigorous activity each week according to the *Physical Activity Guidelines for Americans*<sup>64</sup>. For even greater health benefits, it is recommended to do 300 minutes of moderate intensity or 150 minutes of vigorous

activity each week<sup>64</sup>. There are various objective and self-report tools to measure PA within the current literature. Two common tools found within the literature are the accelerometer, an objective tool, and the 7-Day Physical Activity Record (PAR), a self-report or subjective measure.

A study<sup>65</sup> conducted in 2009 compared a triaxial accelerometer and the 7-Day PAR for measuring time doing PA. This research was conducted within the FRESH START study, a randomized clinical trial amongst breast and prostate cancer survivors targeting diet and exercise. All participants were given accelerometers and asked to complete a 7-Day PAR. Measurements were taken at baseline (n=115), year 1 (n=103), and year 2 (n=99) follow-ups. Sloane et al. found that the 7-Day PAR and accelerometer were moderately correlated based on Pearson Correlation coefficients at baseline (0.54), year 1 (0.53), and year 2 (0.24) with  $p \leq 0.01$  during each time point. However, actual minutes of activity differed greatly between the two measures. This difference between minutes of PA captured during each data collection point is due to the accelerometer detecting all activity on a minute-by-minute basis and the 7-Day PAR being a self-reported estimation of minutes spent on moderate to vigorous activity during the week for at least 10 minutes at a time<sup>65</sup>. While the accelerometer has been shown to be a more accurate measure of time spent on PA, the 7-Day PAR was used in the initial ELMM study. While the limitations of self-reported tools are well known<sup>66,67</sup>, the 7-Day PAR remains a valid<sup>27</sup> tool for measuring weekly PA. There are many other wearable devices than the accelerometer to measure PA, however, within the present study none were used to measure PA.

### *Sleep Duration*

The definitions of short, adequate/average, and long sleep duration have been defined in the literature. Surveys distributed by the Centers for Disease Control and Prevention have defined short sleep duration as <7 hours<sup>68</sup>, while Healthy People 2020 has defined 7 hours as adequate for adults aged  $\geq 22$  and a minimum of 8 for adults aged 18-21. For this secondary data analysis, 7-8 hours of sleep was used for adequate sleep duration due to variation in population age, <7 as short and  $\geq 9$  as long based upon the literature.

Within an overweight and obese population, there are a few extraneous factors that may influence total sleep duration. As it has been observed that the rate of overweight and obesity has increased significantly in recent decades, there has been a per night decrease in the average sleep duration of Americans by 1-2 hours<sup>4</sup>. Further, a recent representative survey from 2008 suggests that 35-40% of adult Americans reportedly sleep <7 hours on weeknights<sup>69</sup>. One of the factors influencing shorter sleep duration within this overweight and obese population may be Obstructive Sleep Apnea (OSA)<sup>42</sup>. OSA typically leads to sleep deprivation due to periodic sleep interruptions throughout a sleep opportunity. Another factor that may affect sleep duration is depression.

Within the literature<sup>39</sup>, it has been discussed that short or long sleep duration may be predictive or increase relative risk of depression. There are a few mechanisms that are believed to drive relative risk. One explanation is that restrictive sleep contributes to daytime tiredness<sup>70</sup>, which has been found to be a predictor of depression<sup>71</sup>. Further, with increased daytime tiredness may come negative feelings or emotions and events that can eventually lead to depressive attitudes<sup>72</sup>. When considering longer sleepers, there is a correlation with reduced PA<sup>73</sup>, which may influence an increased risk for depression. PA

has many risk reducing mechanisms for depression, including: increasing levels of neurotransmitters of dopamine and serotonin<sup>74</sup>, increased endorphin secretion<sup>75</sup>, distraction from stressful events or tasks<sup>76</sup>, or improvement in self-esteem<sup>77</sup>. While OSA and depression may have an affect on sleep duration, the present data analysis did not assess or screen for OSA or depression, as sleep was not an outcome of the original study.

Both short and long sleep durations have been associated with poor health outcomes across the research. These outcomes include: obesity<sup>5</sup>, type 2 diabetes<sup>78</sup>, coronary heart disease<sup>79</sup>, hypertension<sup>80</sup>, and premature death<sup>81</sup>. Inadequate sleep duration has been associated with increased and excessive kcal intake consistently within the literature, leading to positive energy balance and higher BMI. Factors that may cause this excessive kcal intake due to inadequate sleep duration are: increased time and mealtime opportunities, psychological distress or perceived stress, increased psychological food reward mechanism, decreased dietary restraint, increased energy needed to sustain longer wake time, and increased hunger hormones<sup>82</sup>. It has been inferred that the association between higher BMI and decreased sleep duration is due to increased total kcal intake, or increased time and opportunities for eating, rather than decreased PA<sup>12</sup>.

It is important to note that there is a “U” shaped association between sleep duration and BMI, as well as most other poor health outcomes. There is a certain point in which restrictive<sup>83</sup> or excessive sleep duration is associated with a higher BMI, typically <7 hours. However, sleep >7 hours has not been consistently associated with a higher, unhealthier BMI. The notion that excess sleep is attributed with unhealthy behaviors is



supported by Xiao et al., in a cross-sectional study among women within five years of childbirth; their results indicate that longer sleep duration is associated with lower diet quality and higher BMI<sup>84</sup>. Regardless of short or long sleep duration, as it has continued to be studied, it appears that sleep duration has mostly been observed within the context of weight gain with little attention on its effect on weight loss.

Many studies have explored weight gain<sup>12, 13, 14</sup> or weight gain prevention<sup>15</sup> and sleep duration. A systematic literature search<sup>5</sup> of epidemiological evidence for short sleep duration and weight gain indicates that the literature has consistently shown that restricted sleep is correlated with weight gain. This weight gain is often attributed to the correlation of restricted sleep and excessive kcal intake, or positive energy balance. Markwald et al. quantified the effects of inadequate sleep duration within their 14-15 day clinical crossover study (n=16) consisting of equal parts healthy men and women. One week prior to experimentation, all participants were given a 9-hour sleep opportunity. Three days prior to the study, participants were provided a diet based on their estimated needs (metabolic rate x 1.5 activity factor) and instructed to only eat the food provided and nothing else, other than water. After the week of 9-hour sleep opportunity, the participants were given a 5-hour sleep opportunity for 5 days, in order to simulate a workweek. After this period of inadequate sleep, subjects were transitioned back to 9-hour sleep opportunities. It was found that inadequate sleep duration only increased energy expenditure by ~5%, however, energy intake went in excess of energy needed for weight maintenance. Ultimately, inadequate sleep led to a 0.82 kg ( $\pm 0.47$ ) weight gain amongst total participants<sup>85</sup>. However, when participants were transitioned from inadequate to adequate sleep, a -0.03 kg ( $\pm 0.5$ ) weight loss was observed<sup>85</sup>. These data

indicate that sleep duration has physiological and behavioral mechanisms that effect energy balance.

Sleep restriction and its effect on weight loss has also been studied by other researchers<sup>86,87</sup>. A 14-day randomized control trial<sup>87</sup>, conducted by Nedeltcheva et al., studied the effects of sleep restriction on a calorie-restricted weight loss intervention in 10 overweight, middle-aged, nonsmoking adults. The control group was given an 8.5 hour sleep opportunity, while the experimental group only given a 5.5 hour opportunity. Both groups saw equal success in total weight loss of a 3kg average per subject, however the composition of the mass lost by both groups differed. Those with the restricted allotment of sleep did not see as much fat loss (0.6 of 3kg) as their control group counterparts (1.4 of 3kg). These findings suggest that sleep duration is an important contributor in retaining fat-free or lean body mass during negative energy balance. Few studies to date have observed change in sleep duration as a result of a weight loss intervention.

Sleep duration has been shown to be an important factor to consider within the context of weight loss interventions. Sleep is often regarded as one of the pillars of health. However, there are few studies that have investigated self-reported sleep duration as an outcome of a weight loss intervention. One of the few studies<sup>16</sup> that observed change in sleep duration as an outcome of a weight loss intervention did not included sleep as a part of the intervention, much like this data analysis. The intervention consisted of weekly 1-hour group meetings, a caloric-restriction recommendation, a fat gram goal, and a progressive PA goal of 200 min/week; while the control group was provided four 1-hour group sessions. O'Brien et al. did not find significance with sleep as a predictor of

weight loss or a significant difference between control or experimental groups with sleep. Further still, other studies that investigated the relationship of sleep and weight loss as a primary outcome, sleep duration is studied as a predictor<sup>57,58</sup> of weight loss rather than an outcome of an intervention.

There are, of course, a few ways to measure sleep duration. There are many validated tools for measuring self-reported sleep duration; The Pittsburgh Sleep Quality Index<sup>88</sup>, the Athens Insomnia Scale<sup>89</sup>, and the Sleep Timing Questionnaire<sup>90</sup>, to name a few. All of the previously mentioned studies are validated against objective sleep tools, such as the actigraphy<sup>91</sup>. However, the 7-Day PAR was used within the initial study that this secondary data analysis is using for analyses and has not been validated for sleep duration against the actigraphy. Ultimately, self-reported measures of sleep duration have been previously studied against objective measures, therefore the 7-Day PAR is an appropriate tool to measure self-reported sleep duration.

#### *Sleep Duration and Diet Quality*

To date, very little has been studied on the relationship between sleep duration and diet quality, assessed by validated diet quality indices. There are two cross-sectional studies that have researched these variables. Stern et al. found that postmenopausal women in the Women's Health Initiative prospective Observational Study sleeping  $\leq 6$  hours had lower quality diets than women sleeping at least 7 hours each night. Within this study, diet quality was assessed by the 2005 AHEI, however, BMI was not an outcome compared with sleep duration and diet quality<sup>92</sup>. Haghidoost et al. found similar results in which women with a sleep duration of  $< 6$  hours per night had significantly lower diet quality scores. Unlike Stern et al., this study researched associations between sleep

duration, diet quality, and BMI. They found that women with shorter sleep durations, in the lowest quartile (<6 hours/day) had comparatively higher BMI ( $23.2 \pm 3.2$  vs.  $21.1 \pm 2.0$  kg/m<sup>2</sup>;  $p=0.0001$ ) and waist circumference ( $p=0.0001$ ) than those reporting within the highest quartile for sleep duration (>8 hours/day)<sup>9</sup>. Both of these studies reflect that sleep duration is positively correlated with diet quality. However, there has been one study that reported no correlation between sleep duration and diet quality.

Within a study<sup>29</sup> using a cross-sectional probability sample and self-report data from a community-based cohort study of hispanics/latinos in the US, the Hispanic Community Health Study/Study of Latinos (n=11888), diet quality was compared by sleep duration. Mossavar-Rahmani et al. found that diet quality (as assessed by the 2010 AHEI), compared by sleep duration category, did not differ between the sleep duration categories. This is only one study, among many, studying sleep duration and diet quality that does not support the notion that sleep duration and diet quality are correlated. In fact, the idea that diet quality may effect sleep duration has been considered within the literature as well.

Although the literature is mixed, there have been many studies that support the notion that diet, or certain foods, may effect sleep duration. Some foods have been anecdotally said to improve sleep, such as milk, herbal products, or certain types of fruits<sup>82</sup>. However, within the literature, there are mixed results. A few studies validate the idea that milk can improve sleep<sup>93</sup>, while others are unable to support this notion<sup>94</sup>. Similar to these food items, the amino acid, tryptophan (found in turkey meat and other foods), has been said to improve or induce sleep. It has been found, that in clinical doses of tryptophan, the literature supports that tryptophan may induce or improve sleep based

upon the underlying mechanism this amino acid plays in sleep and alertness<sup>95</sup>. In addition to tryptophan, B vitamins and minerals, such as magnesium, may effect sleep based upon their influence on the secretion of melatonin, which also effects sleep and alertness<sup>95</sup>. Despite these findings, there can be no conclusions drawn from the current body of evidence in regard to certain food items definitively improving sleep quality or duration. Regardless of sleep duration effecting diet quality or the alternative, these variables have yet to be adequately studied before and after a weight loss intervention.

#### *Wearable Bite Counter Device and Self-Monitoring*

Wearable devices are used to automatically and quantitatively monitor eating activities and PA<sup>28</sup>. Such devices can be used to self-monitor bite count and aid users monitor and control eating rate<sup>21,28</sup>. Self-monitoring requires an individual to record dietary intake or PA in order for that person to regulate or be aware of their behaviors<sup>96</sup>. Self-monitoring has consistently been shown to aid in weight loss<sup>19</sup>, especially when combined with goal setting. The intentional act of self-monitoring heightens self-awareness of food consumption and daily activity that otherwise may have been overlooked, allowing the individual to adjust these behaviors in order to achieve a goal<sup>97</sup>. Technologies, such as the ELMM, have been developed in order to make self-monitoring eating activities, energy intake, and PA more attainable and user friendly.

As a result, wearable devices such as the ELMM have been implemented in weight loss interventions. The ELMM is an emerging device within the wearable device community, with the first generation debuting in 2011 and the second version, now available to the public, in 2015. As this device is still developing, little has been studied

regarding behavior change, such as improved diet quality, with the application of a wearable device in free-living scenarios.

The ELMM device, also known as the Bite Counter, is a wearable ambulatory device that tracks bites of food taken and number of steps throughout the day. The device is able to track number of bites by the wrist motions on the wrist the device is worn via gyroscope and an algorithm<sup>98</sup>. This device has been validated for bite and step counting purposes in free-living<sup>99</sup> and lab-based<sup>100</sup> scenarios. However, it has been shown that this device may underestimate number of bites with most foods and beverages, and over records number of bites when cutting food with a knife and fork<sup>100</sup>. Another limitation identified within the literature is that the device is not entirely automated, the user is required to turn “on” and “off” the bite counting feature<sup>21</sup>. Rather, these limitations are to be considered if further analysis is to be done with data collected from the ELMM devices worn by participants in future studies. As the technology is still emerging, there are few studies that use the ELMM device within an intervention.

Studies that have incorporated the bite-counter within their research have looked at a few variables that this device may affect. Jasper et al. studied if the presence of the bite-counter along with the feedback captured by the device and if the presence of the device along with goal setting would lead to altered eating behavior<sup>101</sup>. Another study<sup>21</sup> investigated the relationship between bite count and energy intake, and if there are sex and BMI differences in kcal per bite within free-living scenarios. A more recent study<sup>28</sup>, conducted in 2016 by Salley et al., utilized a tethered version of the Bite Counter and studied self-reported kcal estimates versus the kcal recorded via the tethered device. While each of these studies indicate that this device may be valuable within weight loss

programs and reducing total kcal consumption, none of these studies implement the Bite Counter or EMM device within a weight loss intervention, with weight loss as a primary outcome.

Recently, however, a study<sup>43</sup> has been published with weight loss between groups as the primary outcome of a self-monitoring based intervention. Turner-McGrievy et al. conducted a mobile weight loss intervention that persisted for 6 months. Participants were randomized into either the Bite Counter group (n=39) or the mobile dietary app group (n=42) and given calorie or bite count restriction. Most participants (48%) were assigned 1500kcal/d; other participants were assigned 1800kcal/d (17%) or 1200kcal/day (38%). The DIET Mobile Study provides nutrition education to the participants throughout the course of the study regardless of group assignment. This study distributed information twice a week via podcasts. Both groups were asked to complete two dietary recalls through the ASA24 site as well as a PA questionnaire. These data were used to compare mean energy intake to mean energy expenditure between groups pre- and post-intervention. Ultimately, this study found that those in the app group ( $-6.8 \pm 0.8$ kg) had more weight loss success than the Bite Counter group ( $-3.0 \pm 0.8$ kg) from month 0 to 6 ( $P < 0.001$ ). While the DIET Mobile Study collected dietary information from participants using the ASA24 this data was not utilized for the purposes of measuring dietary quality, an invaluable piece to weight loss success. Additionally, while this study focuses on self-monitoring as an influencer on behavioral weight loss, few behavioral outcomes are observed.

The DIET Mobile Study is one of the first weight loss interventions to add a nutrition education piece incorporating this wearable device, with weight loss being a

primary outcome. As mentioned before, diet quality is an important factor in weight loss interventions. However, Salley et al. note that a wearable device alone cannot promote diet quality<sup>28</sup>, as it is as tool to mostly help control portion sizes or number of bites. Therefore, it is necessary to analyze the association of diet quality with a wearable self-monitoring device and a nutrition education intervention. It may be possible that the introduction of a device may help improve the diet quality of an individual with the addition of a nutrition education piece. However, diet quality has yet been observed in a weight loss intervention utilizing the ELMM device.

### *Conclusion*

The rate at which average adult BMI is increasing within the US needs to continue to be confronted. One of the only ways to reduce the incidence of overweight and obesity is to healthfully promote behaviors that would lead provide those individuals with an unhealthy BMI or weight to a state of negative energy balance. Common weight loss interventions seen are caloric-restriction based. Many of these calorie-restriction interventions have other components that are focused on as well, such as diet quality and PA. However, a variable not seen as frequently within weight loss interventions but has been correlated with BMI and predictive of weight loss success is sleep duration. Weight loss interventions have utilized self-monitoring of PA and energy intake as an effective tool during weight loss throughout the literature. This is because self-monitoring has become easier for individuals to consistently use as technology, such as the ELMM device, has emerged. There is a need for research regarding sleep duration and diet quality within the context of a weight loss intervention utilizing emerging self-monitoring technology that the literature has yet to produce.



## APPENDIX B: Informed 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<sup>2</sup> or greater than 37 mg/kg<sup>2</sup>
- 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.
- ❖ 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 C: 7-Day Physical Activity Form

**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**

		1	2	3	4	5	6	7
<b>SLEEP</b>		1 __	2 __	3 __	4 __	5 __	6 __	7 __
<b>M O R N I N G</b>	Moderate							
	Hard							
	Very Hard							
<b>A F T E R N O O N</b>	Moderate							
	Hard							
	Very Hard							
<b>E V E N I N G</b>	Moderate							
	Hard							
	Very Hard							
<b>Total Min Per Day</b>	<b>Strength:</b>							
	<b>Flexibility:</b>	_____	_____	_____	_____	_____	_____	_____

- 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

<b>Worksheet Key:</b>	<b>Rounding:</b> 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	

**INTERVIEWER:**

Please answer questions below and note any comments on interview.

5. Were there any problems with the 7-Day PAR interview? 0. No  
1. Yes (If yes, please explain.)

Explain any problems you had with this interview:

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6. Do you think this was a valid 7-Day PAR interview? 0. No  
1. Yes

7. Please list below any activities reported by the subject which you don't know how to classify.

---

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8. Please provide any other comments you may have in the space below.

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APPENDIX D: 24-Hour Dietary Recall Form

24-Hour Dietary Recall

Interviewee:

Date:

Interviewer:

Day:

Time	Food	Portion

Was today’s intake in anyway unusual?

Did you take any supplements today? If so, please specify brand, amount, and type.

APPENDIX E: Additional Tables

Var	Group	Pre	Post	Change	TimexGroup		Time	
		Mean (± SD)	Mean (± SD)	Mean (± SD)	F	Eta Sq	F	Eta Sq
Weight (kg)	Ex n=37	88.9 (14.2)	88.1 (14.6) <sup>a</sup>	-0.8 (2.2)	0.225	0.003	**8.434	0.108
	Cx n=35	89.6 (14.6)	89.0 (14.7)	-0.6 (1.8)				
Sleep (hr/d)	Ex n=37	7.6 (0.9)	7.7 (0.9)	0.1 (1.0)	0.025	0.000	1.286	0.019
	Cx n=35	7.6 (0.9)	7.7 (0.9)	0.1 (0.7)				
MVPA (min/ wk)	Ex n=37	255.5 (227.2)	285.0 (227.4)	29.6 (289.3)	0.072	0.001	1.185	0.017
	Cx n=35	299.5 (226.9)	348.4 (262.4)	48.9 (323.0)				
Avg EI (kcal/d)	Ex n=37	2025.8 (606.7)	1790.6 (637.2) <sup>a</sup>	-235.2 (552.6)	2.962	0.041	*4.126	0.056
	Cx n=35	1874.3 (585.9)	1854.0 (529.3)	-19.5 (508.7)				
HEI	Ex n=37	54.3 (12.6)	55.8 (14.5)	1.5 (9.5)	0.066	0.001	2.504	0.035
	Cx n=35	54.4 (7.9)	56.1 (10.5)	2.0 (9.4)				

Var – Variable, Sleep – sleep duration, hr – hour, d – day, MVPA – moderate-to-vigorous physical activity, min – minutes, wk – week, Avg EI – average energy intake, HEI – dietary quality, Ex – Experimental, Cx – Control ; \*p<0.05, \*\*p<0.01; Intent to Treat Analysis; 2-way repeated measures ANOVA; Within Group Paired T-Test Significance<sup>a</sup>; <sup>a</sup>p<0.05



Table 6. Baseline Differences Between Groups – Completers			
Variable	F	df	p
Weight (kg)	0.010	62	0.902
BMI (kg/m <sup>2</sup> )	0.732	62	0.795
Waist Circumference (cm)	0.056	62	0.820
%BF	0.039	62	0.682
Sleep (hr/d)	0.266	62	0.339
MVPA (min/wk)	0.005	62	0.331
Avg EI (kcal/d)	0.621	62	0.187
HEI	7.831	62	0.925
*p<0.05, **p<0.01; Completers Analysis; Independent T-Test			

Table 7. Baseline Differences Between Groups – Intent to Treat			
Variable	F	df	p
Weight (kg)	0.170	70	0.851
BMI (kg/m <sup>2</sup> )	0.154	70	0.687
Waist Circumference (cm)	0.000	70	0.795
%BF	0.062	70	0.417
Sleep (hr/d)	0.003	70	0.411
MVPA (min/wk)	0.045	70	0.414
Avg EI (kcal/d)	0.844	69	0.286
HEI	8.136	69	0.944
*p<0.05, **p<0.01; Intent to Treat; Independent T-Test			

Table 8. Differences Between Groups, Post-Intervention – Completers			
<b>Variable</b>	<b>F</b>	<b>df</b>	<b>p</b>
Weight (kg)	0.062	62	0.812
BMI (kg/m <sup>2</sup> )	1.760	62	0.588
Waist Circumference (cm)	0.817	62	0.898
%BF	0.047	62	0.656
Sleep (hr/d)	1.003	59	0.842
MVPA (min/wk)	0.283	62	0.287
Avg EI (kcal/d)	0.306	62	0.555
HEI	4.463	62	0.981
*p<0.05, **p<0.01; Completers Analysis; Independent T-Test			

Table 9. Differences Between Groups, Post-Intervention – Intent to Treat			
<b>Variable</b>	<b>F</b>	<b>df</b>	<b>p</b>
Weight (kg)	0.057	70	0.803
BMI (kg/m <sup>2</sup> )	0.735	70	0.564
Waist Circumference (cm)	0.435	70	0.823
%BF	0.006	70	0.459
Sleep (hr/d)	0.221	67	0.821
MVPA (min/wk)	0.916	70	0.277
Avg EI (kcal/d)	0.769	69	0.625
HEI	3.91	69	0.906
*p<0.05, **p<0.01; Intent to Treat; Independent T-Test			

Group	Variable	Mean Change (± SD)	95% CI	t	df	p
Ex n=29	Weight (kg)	-1.0 (2.4)	-1.95,-0.11	-2.29	28	*0.030
	BMI (kg/m <sup>2</sup> )	-0.5 (0.8)	-0.78, -0.18	-3.26	28	**0.003
	Waist Circumference (cm)	-0.8 (3.6)	-2.18, 0.58	-1.18	28	0.247
	%BF	-1.0 (2.1)	-1.80, -0.21	-2.59	28	*0.015
	Sleep (hr/d)	0.2 (1.1)	-0.27 0.62	0.82	27	0.421
	MVPA (min/wk)	37.8 (327.6)	-86.80, 162.39	0.62	28	0.539
	Avg EI (kcal/d)	-300.1 (610.3)	-532.27, -67.99	-2.65	28	*0.013
	HEI	1.9 (10.8)	-2.22, 5.98	0.94	36	0.355
Cx n=35	Weight (Kg)	-0.6 (1.8)	-1.21, 0.54	-1.86	34	0.072
	BMI (Kg/m <sup>2</sup> )	-0.2 (0.7)	-0.47, 0.1	-1.93	34	0.062
	Waist Circumference (cm)	-0.5 (3.9)	-1.89, 0.81	-0.81	34	0.422
	%BF	-0.9 (1.6)	-1.45, -0.35	-3.31	34	**0.002
	Sleep (hr/d)	0.1 (0.7)	-0.15, 0.36	-0.83	32	0.415
	MVPA (min/wk)	48.9 (323.0)	-62.02, 159.9	0.90	34	0.376
	Avg EI (kcal/d)	-19.5 (508.7)	-194.20, 155.29	-0.23	34	0.822
	HEI	2.0 (9.4)	-1.16, 5.26	1.3	34	0.204

Ex – experimental, Cx – control, Cm – centimeters, %BF – percent body fat measured by BodPod, Sleep – sleep duration, hr – hour, d – day, MVPA – moderate-to-vigorous physical activity, min – minutes, wk – week, Avg EI – average energy intake, HEI – dietary quality; \*p<0.05, \*\*p<0.01; Completers Analysis; Paired T-Test

Group	Variable	Mean Change (± SD)	95% CI	t	df	p
Ex n=37	Weight (kg)	-0.8 (2.2)	-1.53, -0.08	-2.25	36	*0.031
	BMI (kg/m <sup>2</sup> )	-0.4 (.7)	-0.61, -0.13	-3.15	36	**0.003
	Waist Circumference (cm)	-0.6 (3.2)	-1.70, 0.45	-1.18	36	0.245
	%BF	-0.8 (1.9)	-1.42, -0.16	-2.54	36	*0.016
	Sleep (hr/d)	0.1 (1.0)	-0.20, 0.48	0.82	35	0.419
	MVPA (min/wk)	29.6 (289.3)	-66.84, 126.08	0.62	36	0.537
	Avg EI (kcal/d)	-241.8 (559.0)	-430.91, -52.64	-2.59	35	*0.014
	HEI	1.5 (9.7)	-1.75, 4.79	0.94	35	0.353
Cx n=35	Weight (kg)	-0.6 (1.8)	-1.21, 0.05	-1.86	34	0.072
	BMI (Kg/m <sup>2</sup> )	-0.2 (0.7)	-0.47, 0.01	-1.93	34	0.062
	Waist Circumference (cm)	-0.5 (3.9)	-1.89, 0.81	-0.81	34	0.422
	%BF	-0.9 (1.6)	-1.45, -0.35	-3.31	34	**0.002
	Sleep (hr/d)	0.1 (0.7)	-0.15, 0.36	0.83	32	0.415
	MVPA (min/wk)	48.9 (323.0)	-62.02, 159.91	0.90	34	0.376
	Avg EI (kcal/d)	-19.5 (508.7)	-194.20, 155.29	-0.23	34	0.822
	HEI	2.1 (9.4)	-1.16, 5.26	1.3	34	0.204

Ex – experimental, Cx – control, Cm – centimeters, %BF – percent body fat measured by BodPod, Sleep – sleep duration, hr – hour, d – day, MVPA – moderate-to-vigorous physical activity, min – minutes, wk – week, Avg EI – average energy intake, HEI – dietary quality; \*p<0.05, \*\*p<0.01; Intent to Treat; Paired T-Test

Table 12. Sample Correlations, Change Variables – Intent to Treat			
<b>Variable n=64</b>	<b>Mean Change (± SD)</b>	<b>Correlation with HEI r, p</b>	<b>Correlation with SD r, p</b>
Weight (kg)	-0.7 (2.0)	-0.149, 0.213	0.183, 0.135
BMI (kg/m <sup>2</sup> )	-0.3 (0.7)	-0.153, 0.204	0.115, 0.349
Waist Circumference (cm)	-0.6 (3.6)	-0.097, 0.419	*0.240, 0.048
%BF	-0.9 (1.8)	-0.201, 0.092	0.070, 0.568
Sleep (hr/d)	0.1 (0.9)	-0.169, 0.169	
MVPA (min/wk)	39.6 (306.3)	-0.183, 0.126	-0.100, 0.418
Avg EI (kcal/d)	-132.2 (542.6)	-0.210, 0.079	0.060, 0.628
HEI	1.8 (9.5)		-0.169, 0.169
Cm – centimeters, %BF – percent body fat measured by BodPod, *p<0.05, **p<0.01; Intent to Treat; Pearson’s Correlations			

Table 13. Sample Correlations, Post-Intervention – Completers			
<b>Variable n=64</b>	<b>Week 8 Mean (+ SD)</b>	<b>Correlation with HEI r, p</b>	<b>Correlation with SD r, p</b>
Weight (kg)	88.6 (15.1)	*-0.290, 0.020	0.073, 0.576
BMI (kg/m <sup>2</sup> )	31.0 (3.4)	-0.070, 0.585	0.095, 0.469
Waist Circumference (cm)	102.7 (10.2)	-0.179, 0.156	0.149, 0.252
%BF	37.1 (8.8)	0.241, 0.055	0.009, 0.946
Sleep (hr/d)	7.7 (0.9)	-0.058, 0.658	
MVPA (min/wk)	316.9 (257.5)	0.076, 0.551	-0.018, 0.892
Avg EI (kcal/d)	1816.1 (571.1)	**-.0356, 0.004	0.237, 0.065
HEI	56.5 (12.5)		-0.058, 0.658
Cm – centimeters, %BF – percent body fat measured by BodPod, *p<0.05, **p<0.01; Completers Analysis; Pearson’s Correlations			

Table 14. Sample Correlations, Post-Intervention – Intent to Treat			
Variable n=72	Week 8 Mean (+ SD)	Correlation with HEI r, p	Correlation with SD r, p
Weight (kg)	88.5 (14.5)	-0.226, 0.058	0.079, 0.518
BMI (kg/m <sup>2</sup> )	31.0 (3.3)	-0.038, 0.751	0.100, 0.412
Waist Circumference (cm)	102.8 (10.0)	-0.159, 0.186	0.151, 0.216
%BF	36.7 (8.7)	*0.235, 0.049	0.006, 0.961
Sleep (hr/d)	7.7 (0.9)	-0.087, 0.479	
MVPA (min/wk)	315.9 (245.4)	0.065, 0.587	-0.007, 0.952
Avg EI (kcal/d)	1819.9 (588.0)	**-.0.317, 0.007	0.221, 0.070
HEI	56.3 (12.6)		-0.087, 0.479
Cm – centimeters, %BF – percent body fat measured by BodPod, *p<0.05, **p<0.01; Intent to Treat; Pearson’s Correlations			

Table 15. Sample and Within Group HEI Component Scores, Pre- to Post- Intervention – Intent to Treat					
Variable (Possible Score)	Mean Change ( $\pm$ SD) n=72	Ex Mean Change ( $\pm$ SD) n=37	Cx Mean Change ( $\pm$ SD) n=35	95% CI	t
Total Fruits (5)	0.15 (1.4)	0.28 (1.2)	0.00 (1.6)	-0.18, 0.48	0.896
Whole Fruits (5)	0.10 (1.7)	0.19 (1.6)	0.00 (1.8)	-0.30, 0.50	0.489
Total Vegetables (5)	0.02 (1.2)	-0.26 (1.3)	0.31 (1.2)	-0.28, 0.31	0.112
Greens and Beans (5)	-0.07 (1.6)	-0.48 (1.5)	0.36 (1.7)	-0.45, 0.31	-0.391
Whole Grains (10)	0.12 (2.8)	0.39 (2.6)	-0.17 (3.0)	-0.53, 0.77	0.362
Dairy (10)	0.10 (2.6)	0.01 (2.4)	0.2 (2.9)	-0.52, 0.72	0.322
Total Protein Foods (5)	0.16 (0.88)	0.16 (0.9)	0.16 (0.8)	-0.04, 0.37	1.565
Seafood and Plant Proteins (5)	-0.03 (1.6)	-0.36 (1.6)	0.33 (1.6)	-0.41, 0.36	-0.137
Fatty Acids (10)	*0.73 (2.8)	*0.92 (2.6)	0.54 (3.1)	0.07, 1.40	2.196
Refined Grains (10)	0.22 (2.7)	0.29 (2.5)	0.16 (3.0)	-0.42, 0.86	0.696
Sodium (10)	*-0.56 (2.2)	-0.49 (1.9)	-0.65 (2.4)	-1.08, -0.05	-2.200
Added Sugars (10)	-0.01 (2.0)	-0.29 (1.9)	0.28 (2.1)	-0.48, 0.46	-0.060
Saturated Fats (10)	**0.84 (2.5)	*1.12 (2.5)	0.54 (2.5)	0.25, 1.42	2.858

Ex – experimental group, Cx – control group; degrees of freedom were 71 for all variables; \*p<0.05, \*\*p<0.01; Intent to Treat Analysis; Paired T-Test



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