ASSESSING THE BITE COUNTER AS A WEIGHT LOSS TOOL

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ASSESSING THE BITE COUNTER AS A WEIGHT LOSS TOOL

A Thesis
Presented to
the Graduate School of
Clemson University

In Partial Fulfillment
of the Requirements for the Degree
Master of Science
Applied Psychology

by
Michael Lee Wilson
May 2014

Accepted by:
Dr. Eric R. Muth, Committee Chair
Dr. Adam W. Hoover
Dr. Patrick J. Rosopa
ABSTRACT

Obesity is a growing health concern throughout the world. Health risks associated with obesity such as diabetes and heart disease result in obesity costing us over $170 million annually. Self-monitoring of Energy Intake (EI) is a critical element of a successful weight loss plan; however current methods to monitor EI are cumbersome and prone to under reporting. The primary purpose of the study was to develop and test an experimental diet protocol based on user feedback from the Bite Counter. A secondary purpose was to examine if this protocol would affect meaningful weight loss by device users. Data were collected from 30 participants (15 control) in a study where Bite Counter feedback was used to titrate daily bite count goals in order to meet a 1 to 2 pound per week weight loss goal measured against the control group which was only given weight loss literature. 77% of our participants were able to use the device to self-monitor a majority of the eating activities. Although weight loss was higher in the Bite Counter group, we determined that a diet protocol based solely on using the Bite Counter did not produce statistically significant weight loss over the ten-week study period. The Bite Counter was able to help the control group sustain their weight loss throughout the entire study period. The study determined that aggressive screening measures during study uptake is needed in order to ensure the recruitment of participants who are likely to complete future studies. User profile personas were developed to assist future researchers identify and classify users as successful or unsuccessful candidates for losing weight using the Bite Counter.
ACKNOWLEDGEMENTS

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CHAPTER ONE
INTRODUCTION

Purpose

The primary purpose of the study was to develop and test an experimental diet protocol based on user feedback from the Bite Counter. A secondary purpose was to examine if this protocol would affect meaningful weight loss by device users.

Motivation for the Current Work: The Obesity Pandemic

Obesity in the World

Obesity rates throughout the world are increasing. Often thought to be a problem germane to developed countries, obesity is now a worldwide pandemic threat. In 2005 the World Health Organization estimated that there were one billion overweight (Body Mass Index (BMI) $\geq 25$ kg/m$^2$) individuals and more than 300 million obese (BMI $\geq 30$ kg/m$^2$) worldwide. Further, they estimated that this figure will grow 50% by 2015 (World Health Organization, 2009). There is no doubt that obesity is a problem that will have lasting effects on the world for the foreseeable future, especially within the US population.

Obesity in the United States

Obesity rates are increasing in the United States at an alarming rate. In fact, the National Health and Nutrition Examination Survey, a national survey conducted by the Centers for Disease Control and Prevention every two years, reported that from 2007 to 2008 researchers found one in three adults in the United States to be overweight with an
additional third of the population reported as obese (Flegal, Carroll, Ogden, & Curtin, 2010). Obesity increases the likelihood of co-morbid diseases including hypertension, heart disease, stroke and cancer (Allison, Fontaine, Manson, Stevens, & VanItallie, 1999). Stuart and colleagues forecast that within the next decade the negative effects of increased obesity will surpass the positive impacts of the reduction of smoking within our society (Stewart, Cutler, & Rosen, 2009). In 2008, the medical costs to treat overweight and obese Americans were estimated to be $170.2 billion (Tsai, Williamson, & Glick, 2011). This means that one-tenth of all health care related spending is used to combat an individual health problem that is largely preventable.

**Understanding and Measuring Energy Balances**

*Understanding Energy Balance*

For stasis, habitual EI (Energy Intake) must equal habitual EE (Energy Expenditure), stated as a ratio: 

\[ \text{EI/EE} = 1.0 \]  

(Livingstone & Black, 2003). In other words, there must be equality between what an individual takes in and what they expend in order to maintain a target weight. Weight loss strategies target either the EE side, the EI side or in some cases both EE and EI. There are numerous methods to scientifically measure both EI and EE, ranging from researcher-controlled complex monitoring methods to using simple belt-worn tools (Ainslie, Reilly, & Westerterp, 2003).

*Measuring EE*

Researchers studying EE in humans have numerous methods at their disposal to measure the amount of energy expended. Doubly labeled water (DLW), heart rate, questionnaires,
activity recall, and accelerometers are many of the validated methods to measure human EE (Ainslie et al., 2003). DLW is expensive and only yields a measurement at the day or week level through laboratory testing (Schoeller, 1995). Self-report questionnaires and dietary recalls are subject to reporting bias (Hill & Davies, 2001; Jonnalagadda et al., 2000). Only recently have individuals and researchers enjoyed the availability of small sensors worn on the body that objectively measure movement activity and have been shown to provide objective reports of human EE (Freedson & Miller, 2000).

*Measuring EI*

Current methods used to measure EI are through the use of DLW, direct observation, food logs and the written dietary recall. The DLW method is the long-held “gold standard” method of estimating EI. As mentioned above, it is really a measure of EE with the EI component being derived by using DLW coupled with weight change at the week level. Hence, the resolution of DLW is limited (Schoeller, 1995). Food logs and dietary recall methods are cumbersome, time-consuming and suffer from under-reporting bias (Jonnalagadda et al., 2000). Until recently, objective, easy to wear devices were not available to measure EI (monitor eating). The Bite Counter, described in more detail below, is such a tool.

*The Bite Counter: A dietary self-monitoring tool for weight loss treatment and research.*

The Bite Counter shown in Figure 1.1 is a new mobile health tool for self-monitoring of intake. This wrist-worn device monitors intake by counting the number of
times a person puts food or drink into their mouth, i.e., takes a bite. The device simply has to be turned on at the start of eating and off at the end of eating. While eating, the

![Figure 1.1. The commercially available Bite Counter.](image)

Bite Counter displays bite count for the current eating activity (EA) in real-time. Between meals, the device has a user review button which when pressed will display the bite count for the last EA and a total bite count for the day. A time-stamped log of bite count data is stored in memory for download to a PC to generate a calendar of EAs for longer term analysis of eating behavior, a sample of which can be seen in Figure 1.2. Hence, the device provides data for real-time self-monitoring of intake during a meal, daily intake self-monitoring, and long term analysis of week-to-week and month-to-month EAs. This allows for behavior change to be targeted at the single meal, e.g., a cue to stop eating before overeating, as well as at longer term eating patterns, e.g., eliminating overeating on weekends compared to weekdays.
Figure 1.2. PC software for visualizing eating activity (EA) data. A month long calendar of EAs recorded by the Bite Counter is shown on the left. Each line represents an EA and the length of the line represents the bite count. A user can click on the calendar to see more detailed information for the week, showing time of day, duration and bites for each EA as well as total bites for the day as seen on the right.

Weight Loss Approaches

Treating Obesity

The National Institutes of Health (NIH) Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults (1998), describes 6 general strategies for weight loss and maintenance. These strategies are: dietary therapy, increased physical activity, behavior therapy, a combination of the previous three strategies, pharmacotherapy, and surgical intervention (National Institutes of Health, 1998). The NIH guidelines recommend at least a six month trial of a combined treatment protocol (dietary therapy and increased physical activity) prior to considering pharmacotherapy treatments. The report also recommends that surgical interventions should only be considered in cases of severe obesity in which other weight reduction efforts or therapies have failed. Hence, the first line of weight loss strategies includes dietary therapy, increased physical activity and behavior therapy.
**Dietary Therapy**

The reduced calorie diet (reducing the EI) is the fundamental tool in dietary therapy approach. Dietary therapies often include the education of individuals on the various elements and information needed to decrease their caloric intake. Traditionally, low calorie diets (LCD), defined as diets consisting of 1,000 to 1,200 kcal/day for women and 1,500 to 1,800 kcal/day for men (National Institutes of Health, 1998), result in a calorie deficit of 500 to 1,000 kcal/day and produce a weight loss of 1 to 2 pounds per week. The 1 to 2 pound per week target is the maximum recommended rate for sustained weight loss (National Institutes of Health, 1998). The efficacy of the LCD is dependent on educational efforts that address several factors including energy values of foods, food composition, nutrition labeling, purchasing habits and food preparation (National Institutes of Health, 1998).

**Increased Physical Activity**

Increased physical activity (increasing EE) improves cardiovascular fitness and decreases cardiovascular disease risks (National Institutes of Health, 1998). Furthermore, it has been demonstrated that when physical activity is used to increase the EE level above the level of EI, weight loss occurs (Livingstone & Black, 2003).

**Behavior Therapy**

Strategies that provide tools for overcoming barriers to compliance with dietary therapy or increased physical activity are helpful in achieving weight loss and
maintenance (National Institutes of Health, 1998). Behavioral recommendations for weight control can only be effective to the extent that they change energy balance. Thus they must increase energy expenditure, decrease energy intake, or both. (Jeffery et al., 2000). In a meta-analysis of pedometers and their effect on increased physical activity, the authors found that pedometer users who were given a goal significantly increased their physical activity over baseline compared to those who were not given a goal (Bravata et al., 2007). This indicates that self-monitoring has a tremendous effect on changing human behavior, and is an important tool for achieving meaningful weight loss.

**Self-Monitoring**

**Overview**

In order to successfully change behavior, individuals must set a goal and have a way of self-monitoring their progress toward that goal. Studies show that individuals who set goals for themselves improved their performance as much as 40% (Bandura & Cervone, 1983). This is true regardless of whether you desire to stop smoking, increase your exercise level, or lose weight.

**Self-Monitoring and Behavioral Change for Weight Loss**

Self-monitoring is beneficial to both reducing the EI and increasing the EE in the energy balance equation for humans desiring to lose weight. In a recent meta-analysis of self-monitoring’s effect on weight loss, Burke found that of the 15 studies he evaluated
that focused on dietary self-monitoring and weight loss, all found significant associations between self-monitoring and weight loss. In fact, the evidence in these studies showed that the amount of monitoring and amount of weight loss were strongly positively correlated (Burke, Wang, & Sevick, 2011). In other words, individuals with more complete monitoring records showed a higher weight loss across the board. This same analysis also reviewed the impact of self-monitoring on physical activity. The findings also showed that individuals who consistently self-monitored their exercise achieved significantly greater weight loss (Burke et al., 2011).

**Self-Monitoring Tools**

Typical energy intake self-monitoring methods are based on self-reporting and include food logs, eating activity journals and the 24 hour dietary recall. These tools are cumbersome and prone to inaccuracies (Coons et al., 2012). Visona & George (2002) examined the ability of dieters and non-dieters to estimate calories. They found that while dieters are better at estimating calorie intake than non-dieters, they still underestimate by about 30% compared to non-dieters who underestimated EI by about 40%. Protocols involving technology-based versions of these self-report methods (e.g., Internet, smart phone) produced significantly greater weight loss compared to controls in a variety of treatment settings utilizing paper-based self-reporting methods (Coons et al., 2012). With the proliferation of smartphones, numerous applications have emerged to enable the tracking of EI, goal setting/progress and EE tracking.
The Bite Counter as a Tool for Self-monitoring of Intake

In research conducted at Clemson University, researchers discovered that while eating, the wrist of a person undergoes a characteristic rolling motion that is indicative of the person taking a bite of food (Hoover, Muth, & Dong, 2010)

![Figure 1.3: Wrist roll motion during the taking of a bite of food occurs regardless of the type of food or utensil.](image)

The Bite Counter Accurately Counts Bites

A research study conducted at Clemson University demonstrated that the Bite Counter accurately counted bites of food eaten during a meal. Experimenters instrumented a table with video cameras, and tethered wrist devices to record raw wrist motion and a video record of what was being consumed during every bite as shown in Figure 1.4. At the bite by bite level, the method was found to detect 82% of bites taken by participants. Some variations in accuracy were observed across different foods, but the biggest variation in accuracy was associated with eating rate (Huang, Z., 2013)
Bite Count is Related to Caloric Intake

In order to measure the utility of using the Bite Counter for estimating caloric intake, a study was conducted at Clemson University in which participants wore Bite Counters for a two week period. For every meal or snack, participants were instructed to use the device to record bite count. Calories were determined from information provided by the participants using the ASA24 dietary recall to provide a record of what was eaten for each meal (Subar et al., 2012). Automatically measured bite count was compared against ASA24 calories for each meal. For 76% of participants the correlation between bites and calories was in the range 0.4 to 0.8 (Scisco, 2012). While there is obviously noise in the kilocalorie-bite relationship for a single bite, due to the energy density of the food being eaten and natural variability in bite size, the relationship shows some stability at the meal level.
In a separate study of bite count and calories, participants’ caloric intake data were examined (Salley, 2013). Participants were asked to report the number of calories they consumed either with or without a menu containing calorie information. Caloric intake information based on bite count was derived using a formula developed during the bite count-ASA24 study described above. This formula transformed bites into calories and was used to calculate a bite count based calorie measure. Errors between true calories and human and bite measured calories were calculated. The results are shown in Figure 1.5. Statistical tests revealed a significant main effect for estimation method, a marginally significant effect for the presence of calorie information, and a significant interaction between estimation method and the presence of calorie information. Calorie estimations based on bite count were significantly more accurate than human measures without the aid of calorie information. The results suggest that bite count has the potential to measure calories when other aids are unavailable, e.g., when eating a meal outside of the home that is prepared and served by someone else with no calorie information available to the individual eating the meal, situations where individuals typically would underreport their caloric intake.
Figure 1.5. Human calorie estimation error (HCE error) with and without calorie information (CI) present versus bite count based calorie estimation error (BCE error) for the same groups.

The Bite Counter is Preferred by Dieters

In data collected at the Medical University of South Carolina Weight Management Center (MUSC WMC), overweight patients were asked to wear Bite Counters for 12 weeks to record their bites during all EAs. Minimal training was provided to the patients with the only instruction being to wear the Bite Counter during all EAs and to turn on the device before taking the 1\textsuperscript{st} bite of food and off after taking the last bite of food. The participants had bi-weekly laboratory visits during which Bite Counter data were downloaded. Compliance was measured as percent of days capturing at least one EA and average EAs/day. The data indicate that some individuals (~20\%) will wear and use the Bite Counter with minimal training, most individuals (~60\%) will be able to wear and use the Bite Counter correctly, but will require training beyond a simple instruction, and some (~20\%) will likely not use the Bite Counter in a way that would accurately track their EAs and will require an alternative approach to using the Bite Counter or a different method for losing weight. Furthermore, data from the Bite
Counter-ASA24 study at Clemson found that 74% of participants preferred using the Bite Counter over a 24-hour recall method, and that the automation provided by the tool could save people an average of 25 minutes per day in estimating and recording energy intake (Scisco, 2012).

**Using the Bite Counter Has the Potential to Help People Lose Weight**

The most important question about the Bite Counter is will it help people lose weight? Pilot tests of Bite Counter Diet protocols were evaluated in another collaborative effort between Clemson and the MUSC WMC. Overweight patients were instructed to wear Bite Counters for 6 weeks to record their number of bites during all EAs. The participants had bi-weekly weigh-ins at which Bite Counter data were downloaded. Participants were divided into two groups, those who received feedback from the Bite Counter and daily bite count targets, and the other group that received no feedback or target bite counts. Although the groups did not differ significantly on weight loss, there was a trend toward greater loss in the feedback group ($M = 4.6$ lbs, $SD = 5.7$ lbs) compared to the no feedback group ($M = 2.6$ lbs, $SD = 1.3$ lbs). The effect size ($d = .43$) was found to approach Cohen’s (Cohen, 1988) standard for a moderate effect ($d = .50$) suggesting that a larger N or longer weight loss period would produce a difference between groups. The data support further research on the Bite Counter as a dietary self-monitoring tool to help individuals reduce intake and thereby lose weight.
The Bite Counter Based Diet

Preliminary results show that males consume on average 17 kilocalories per bite (kpb) and females on average 11 kpb (Scisco, 2012). Reiterating, the Low Calorie Diet (LCD) is defined as diets consisting of 1,000 to 1,200 kcal/day for women and 1,500 to 1,800 kcal/day for men, resulting in a calorie deficit of 500 to 1,000 kcal/day and produce a weight loss of 1-2 lbs/week (National Institutes of Health, 1998). Based on the average kpb from preliminary testing, 100 bites per day would place females and males approximately within the recommended target LCD calorie goals.

Present Study

Overview

The present study examined whether participants who desired to lose weight, could successfully monitor their EI with a Bite Counter and lose weight by reducing their daily bite count. The independent variable (IV) was the presence or absence of bite count feedback. The main dependent variable (DV) in this study was weight change over time.
Hypotheses and Research Questions

Two main hypotheses were tested in this study:

Hypothesis 1: Individuals who received Bite Counter feedback for self-monitoring of EI will have a larger total weight loss than individuals who do not receive feedback.

Hypothesis 2: When bite count feedback is introduced into the control group, weight lost per week will increase, mirroring the weekly weight loss of the feedback condition participants.

In addition, the following three secondary research questions were examined.

Research Question 1: Do participants stop eating when the Bite Counter alarm sounded?

Research Question 2: How long does it take for participants to reach compliance standards?

Research Question 3: What percentage of users cannot comply with using the Bite Counter?
CHAPTER TWO

METHODS

Participants

Sample Size and Recruitment

Forty-eight female participants were recruited for this study from the Clemson University faculty, staff and student population via email, fliers and word of mouth. In order to detect a significant weight loss from the baseline we would need a study size of 14 total participants to be able to reject the null hypothesis that this response difference is different than zero, based on an effect size of 0.43 (derived from pilot testing), power = 0.8, utilizing a one-sample t-test and Type I error rate of 0.05. This study also investigated the differences in weight loss between the feedback and control conditions. In the pilot study, the response within each subject group was normally distributed with standard deviation of 2.17. With the true difference in the experimental and control means of 1.98, we needed to study 20 experimental subjects and 20 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with power = 0.8 and the Type I error probability of 0.05. Pilot testing and compliance analysis of previous studies indicated that approximately 20% of study participants would attrite. The study size was increased to 48 participants in order to allow for non-compliant individuals and drop-outs.
Sample Characteristics, Screening and Compensation

We also limited the study to female participants because of a low respondent rate for males during our pilot testing and to have adequate statistical power for at least one gender. Respondents were screened against the study inclusion criteria of at least 20 pounds overweight with no history of eating disorders. Participants selected were classified as overweight through obese (BMI between 27 and 50) and self-reported as motivated to lose weight. Participants ranged in age from 18 to 65 and were balanced between the feedback and control conditions. Participants were paid $25 for their participation in the study. Participant intake and retention is highlighted in Figure 2.1.

Figure 2.1. Flow diagram of participant recruitment and retention.
The participant group demographics were balance prior to random group assignment as shown in Table 2.2 below.

Table 2.1  Group demographics

<table>
<thead>
<tr>
<th>Group</th>
<th>Age (M/SD)</th>
<th>Height (in.) (M/SD)</th>
<th>Weight (lbs.) (M/SD)</th>
<th>BMI (kg/m$^2$) (M/SD)</th>
<th>Ethnicity (AA/A,H/C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feedback (24)</td>
<td>44.6/13.0</td>
<td>64.6/2.5</td>
<td>191.8/31.7</td>
<td>32.3/5.0</td>
<td>2/2/20</td>
</tr>
<tr>
<td>Control (24)</td>
<td>45.0/13.0</td>
<td>64.5/2.3</td>
<td>195.6/35.7</td>
<td>33.0/5.7</td>
<td>5/0/19</td>
</tr>
<tr>
<td>Group</td>
<td>Age (M/SD)</td>
<td>Height (in.) (M/SD)</td>
<td>Weight (lbs.) (M/SD)</td>
<td>BMI (kg/m$^2$) (M/SD)</td>
<td>Ethnicity (AA/A,H/C)</td>
</tr>
<tr>
<td>Feedback (15)</td>
<td>37.5/17.2</td>
<td>64.1/2.0</td>
<td>191.6/23.0</td>
<td>32.9/4.1</td>
<td>5/0/10</td>
</tr>
<tr>
<td>Control (15)</td>
<td>46.3/10.3</td>
<td>64.4/2.4</td>
<td>191.0/39.2</td>
<td>32.3/5.9</td>
<td>1/1/13</td>
</tr>
</tbody>
</table>

AA = African American, A,H = Asian, Hispanic, C = Caucasian

**Design**

A repeated measures study design lasting 11 weeks (a zero week, and ten weekly weigh-ins) was planned for this study. Pre and post weight change was assessed at the 5 and 10 week marks, given the academic semester environment; timing of breaks (e.g., Thanksgiving break) was likely to lead to dropouts.

This resulted in a mixed study design. First, a between-subjects study design with two conditions: no Bite Counter, NIH printed materials only (the control group) and Bite Counter feedback with goal adjustment with NIH printed materials (the feedback group). In the control group, participants received printed NIH weight loss materials and were shown the Bite Counter, and told they would be given one to use beginning at their fifth follow-up weigh-in meeting. Participants in the control group also reported to the lab for
weekly progress tracking. Second, a within-subjects study design wherein, the control group participants received a Bite Counter after 5 weeks, were given instructions on how to incorporate the device into their dietary planning and use the Bite Counter feedback identical to the feedback condition group. The feedback group participants received printed NIH weight loss materials, a Bite Counter and instructions on how to incorporate the device into their dietary planning and use the Bite Count feedback. Bite Count goals were titrated weekly in order to obtain a weight loss of 1 to 2 pounds.

*Energy Intake Probe*

A dietary intake probe was planned for both groups at the 4 and 12 week points during the data collection period using the ASA24 dietary recall method. This information was collected for validation of compliance and accuracy of EI as measured by the Bite Counter.

*Materials*

*Printed Weight Loss Handouts*

All participants received three publications provided by the U.S. Department of Health and Human Services, National Institutes of Health (NIH). These printed materials are typical of the types of materials that a participant might receive in a clinical setting when weight loss is encouraged. The three publications were:

1. NIH Publication No. 06-5830 (June 2006), “Facts About Healthy Weight”.

   This 4-page, color, 8½” X 11” bi-fold handout provides an overview of health
information related to weight loss (BMI, Heart Disease, Risk Factors, Physical Activity, and Weight Loss). The publication is provided free-of-charge from the NIH.

2. NIH Publication No. 05-5213 (April 2012), “Aim for a Healthy Weight”. This 36-page, color, 8½” X 11” brochure comprehensively addresses all facets of healthy weight loss. The publication is provided free-of-charge from the NIH.

3. NIH Publication No. 10-7415 (April 2012), “Maintaining a Healthy Weight On the Go. This 21-page, color, 5” X 7” pocket guide provides information on dietary choices while eating out.

*Bite Counters*

Bite Counters (Bite Technologies, Clemson, SC) like the one shown in Figure 1.1 were used to count daily bites of food for the participants. The device is a 2.5 x 1.5 inch (64 x 38 mm) plastic rectangle that is 1 inch (25 mm) thick and weighs 2.7 oz (75 grams). A 1-inch (25 mm) wide, 6.5 - 8.5 inches (165 - 216 mm) long wrist band is attached to the device. The battery in the device ideally allowed for 14 hours of bite counting use per charge (approximately 2 weeks of regular use). The Bite Counter stores data for up to 320 eating sessions. A USB connection is used for downloading data and recharging. The Bite Counter operates as a typical watch when not in use counting bites. The device simply has to be turned on at the start of eating and off at the end of eating. While eating it displays bite count for the current eating activity (EA) in real-time. At the end of each eating session, the user again presses the button to turn the device off. Between meals, the
device has a user review button which when pressed will display the bite count for the last EA and a total bite count for the day. A time-stamped log of bite count data is stored in memory for download to a PC to generate a calendar of EAs for longer term analysis of eating behavior. The data include the following for each meal: year, month, day, and time stamp; meal duration; and number of bites taken. These data are viewed through proprietary software available through Bite Technologies. There is also an audible alarm feature that can be set to inform the wearer when a bite limit (either eating session or daily levels) is reached. The alarm continues to sound for each successive bite after reaching the limit until the user manually turns the device off.

**Body Measurements**

**Weight and height**

Weight was measured using the Tanita WB-300 Digital Beam Scale (Tanita Corp., Tokyo, Japan). The scale has an integrated stadiometer that was used to measure the participant’s height.

**Body fat percentage and BMI**

Body fat percentage was measured using the Omron HBF-306, Body Logic Body Fat Analyzer (Omron Corp., Kyoto, Japan). This hand-held device analyzes the impedance of a small electrical current flowing between two electrical plates on the palms of the hands. The current passes more quickly through hydrated fat-free body tissue and extracellular water than fat or bone tissues (McArdle, Katch, Katch, McArdle, & Katch, 1999). Impedance is entered into an equation with height, weight, age, and sex,
resulting in a body fat percentage estimation (Gibson, Heyward, & Mermier, 2000). The Omron Body Logic Body Fat Analyzer provides an accurate estimate of body fat percentage ± 3.5% for approximately 7 out of every 10 men and 2 out of every 3 women when compared to hydrostatic weighing (Gibson et al., 2000). Additionally, the Omron Body Logic Fat Analyzer is a noninvasive and economical way to measure body fat percentage. Also when height and weight parameters are entered into the device it computes a BMI.

**Waist and hip circumference**

The MyoTape™ Tape Measure (Accu-Measure, Greenwood Village, CO) was used to measure waist and hip circumference. To measure waist circumference, the tape measure is wrapped around the smallest circumference around the abdomen. The tape measure is adjusted snugly without causing compressions on the skin. To measure hip circumference, the tape measure is wrapped around the biggest circumference around the buttocks. To measure the waist circumference the tape measure is wrapped around the waist at the navel.

**ASA24 Dietary Recall.**

Dietary recalls were completed using the Automated Self-Administered 24-hour Recall (ASA24) (Subar et al., 2012). The ASA24 is an Internet-based software tool that allows participants to complete 24-hour dietary recalls from a computer without the presence of a researcher. The ASA24 is based on a modified version of the interviewer-administered Automated Multiple Pass Method 24-hour recall developed by the U.S.
Department of Agriculture (USDA) and used in the U.S. National Health and Nutrition Examination Survey (NHANES). The program is available free of charge to researchers. A demo version of ASA24 can be found here: http://asa24demo.westat.com/

**Questionnaires**

**Demographics and Screening**

An on-line pre-screening questionnaire asked participants to report their basic demographics as well as eating frequencies, dieting status and eating order history. Participants were excluded for positive responses to eating disorders questions.

**Useability**

Participants completed a usability questionnaire during their last visit to the laboratory on paper (Appendix E). This questionnaire assessed problems, difficulties, likes, dislikes, and preferences for the Bite Counter.

**Procedure**

**Pre-Screening**

Respondents to recruitment efforts completed an on-line survey. This survey contains an informed consent element, the assignment of a participant number and 11 additional questions about demographics, eating frequency, eating disorder history, current diet program participation and potential meeting times. Participation was limited to respondents with no self-reported history of eating orders and/or no participation in a
current formal diet program (e.g. Weight Watchers®, Jenny Craig, Nutrisystem®, etc…).

Participants were assigned to a respondent pool if no exclusion criteria are met.

Participants were selected from the respondent pool, matched by ethnicity and BMI and then randomly assigned to either the feedback or control group for participation in the study. Participants were notified by email of their selection for the study and the date and time for their orientation meeting.

*Orientation Meeting*

Upon arrival at the meeting, the participant read and signed a Clemson University IRB approved written consent form. The participant was informed of the purpose of the study emphasizing safe weight loss guidelines and was provided the NIH publications. Participants for both the control and feedback groups were given the printed weight loss materials. The experimenter then measured the participant’s height, weight, body fat percentage, hip circumference, and waist circumference. The feedback group participants were also issued a Bite Counter, told how to wear the Bite Counter during the day, how to record bites during a meal, and how to charge the device. In addition, feedback condition participants were provided the written instructions in Appendix A to take home. The experimenter instructed the participant to use the Bite Counter to record all meals and snacks. They were cautioned about casual consumption (a meal or snack consumed over time such as drinking coffee and nibbling on candy for over an hour at one’s desk at work, or drinking a glass of wine in the evening while making dinner). Participants were advised not to record these casual consumption eating activities.
because it increases error. For all participants with a Bite Counter, the device was pre-set to provide the participant with information in two distinct modes. During the “on” or bite count mode the device provided the bite count of the current EA session. During the “off” or data review mode, four pieces of information were enabled: the time of day, bite count during the current meal, bite count total for day and device charge status. Additionally, the alarm was initially set to trigger at 33 bites. Data collection with the Bite Counter began immediately after departing the orientation meeting. The participant was asked if they prefer an email reminder message sent to their preferred e-mail address for weekly meeting reminders and their preferred e-mail delivery time. During the fifth follow-up session, the control group participants were issued a Bite Counter and instructed on its use using the same instructions given to the feedback group participants and both groups were processed in the same manner for the remainder of the 10-week study period.

Data Collection

Follow-up meetings were scheduled weekly with study participants. Follow-up appointments were scheduled for the same day and time each week for consistency. During these meetings weight, body fat percentage, BMI and body measurements were repeated. Additionally, Bite Counter data was downloaded and analyzed for individuals who had been issued a device.
Compliance Screening

The first item examined was the participant’s compliance with using the Bite Counter. Compliance with the Bite Counter was defined as the consistent and daily use of the device to capture eating activities. The goal was to capture all of a participant’s eating activities (EA) during each week-long evaluation period. A compliance analysis was performed on all participants during the weigh-in meeting throughout the study. Compliance was measured by observing the calendar display from the Bite Counter Software shown in Figure 1.2. For screening purposes compliance translated to using the Bite Counter a minimum of 6 of 7 (86%) of available days per week and a minimum of 14 EAs during the 7-day evaluation period. Participants with eating activity who failed this screening test were interviewed to determine if their data were representative of their actual eating activity. If compliance was deemed to be problematic, the participant was educated on the importance of capturing their eating activity and the proper use of the Bite Counter and no changes were made to their bite target value (BTV). Multiple episodes of non-compliance were evaluated for dismissal from the study.

Eating Activity Analysis

Once compliance was determined to have been achieved, eating activity was analyzed by examining the EA calendar such as the example shown in Figure 1.2. This analysis was performed to determine a participant’s eating habits and to actively manipulate BTVs in an effort to influence their EI. The flowchart in Figure 2.2 explains the logic of the eating activity analysis and titration of bite count goals.
To accomplish the BTV adjustment, first a participant’s weight was compared to the previous week’s weight. If weight loss was between 1 and 2 lbs. their BTV was not adjusted. If there was no weight loss or a weight gain, the BTV was decreased by 10 bites. A weight loss of 1 lb. or less called for a BTV decrease of 5 bites. Finally, if an individual’s weight loss was more than 2 lbs., their BTV was increased by 5 bites. All BTV adjustments also resulted in an adjustment of the alarm to a value equal to one-third of the daily bite count total.

![Diagram](image.png)

*Figure 2.2. Eating activity analysis logic flow and goal titration outline.*
Individual Analysis

Each individual participant was evaluated weekly and their BTV was customized. Once a weekly average bite count was established, the EA analysis was conducted one-on-one with each participant. The titration session was interactive, with many of the participants assisting in the adjustment of their BTV based on their performance during the previous week. It should be noted that the logic in the flow chart was only used as an initial guide for conducting the weekly bite count titrations. Once eating patterns were established, participants were questioned about their performance and helped to establish bite target values and alarm settings for the next week.
CHAPTER THREE
RESULTS

Study Attrition

The original study design called for a sample size of forty participants, twenty in each condition. Pilot testing indicated that a dropout rate of 20% could be expected. Participant recruitment included an additional 20% to account for study dropouts. By the completion of study-week eleven, 37.5% (18/48) participants had dropped from the study leaving a sample size of 30 participants, 15 in each condition.

Original Data

Initial examination of the data began with plotting the cumulative weight lost per week for both the feedback and control groups. The graph of these data is displayed below in Figure 3.1. This visualization indicated that the weekly weight losses within the groups were highly varied and inconsistent from week to week.
Figure 3.1 Graph showing cumulative weight loss weekly by group.

Missed Appointments

Participants were scheduled to meet at the same day and time each week. Individuals who knew they were going to miss an appointment were re-scheduled up to three days before or after their original appointment. When participants missed a scheduled appointment, they were contacted via email and asked to come in for a make-up session. Despite these efforts, one-third of study participants missed at least 1 weekly weigh-in appointment over the course of the 11-week study period. For analysis purposes, missing weights were substituted with mean weight value calculated by
averaging the previous and following week’s weight values. Because of these inconsistencies, mean weight loss data were grouped into three distinct periods to facilitate hypothesis testing; the 0-5 weeks, the 5-10 weeks and the 0-10 weeks periods.

Outlier Analysis

Next mean weight loss for the control \( (n = 15, M = -3.61, SD = 7.15) \) and feedback \( (n = 15, M = -2.32, SD = 5.02) \) groups was examined for the 0-10 week period to determine if there were any outliers present in the groups. Histograms of the distributions of both groups were plotted for examination as shown in Figure 3.2 below. Because of the small group sizes and relatively large standard deviations in each group, a parameter of +/- 3 standard deviations was selected to screen for extreme values. Extreme values were further examined to determine if there were additional factors present that contributed to the extreme value. If additional factors were present, the value was deleted from the data set. One participant in the control group was identified as an extreme case. Examination of this participant’s file showed that this individual was losing weight by all means possible. She no longer drove to work opting for the bus to force her to walk around campus, used stairs exclusively instead of elevators, had professed her weight loss intentions to her co-workers resulting in the office no longer bringing in cakes and cookies and had co-workers actively involved in tracking her weekly progress. As a result the individual lost 24.8 pounds in the 11-week period. This case was deleted from the data set prior to making any between group comparisons.
**Testing the Hypotheses**

Hypothesis 1 was that individuals who received Bite Counter Feedback for self-monitoring of EI would have a larger total weight loss than individuals who did not receive Bite Counter feedback. Hypothesis 2 was that when bite count feedback was introduced into the control group, weight loss per week would increase, mirroring the weekly weight loss of the feedback condition participants. To test these hypotheses the total change in weight for the 0-5 week and 5-10 week periods was compared between the feedback and control groups using a 2X2 repeated measures ANOVA (Table 3.2). While there was no main effect for group, $F(1,27) = 0.16, p > .05$; there was a main effect
for time period, $F(1,27) = 4.94, p < .05, \eta^2 = 0.16$. There was also an interaction between time period and group, $F(1,27) = 7.29, p < .05, \eta^2 = 0.21$, as shown in Figure 3.3.

*Table 3.2* Table of means for condition and time.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Weeks 0-5</th>
<th>Weeks 5-10</th>
<th>$M$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feedback</td>
<td>-2.56, 2.59</td>
<td>0.24, 3.46</td>
<td>-1.16</td>
</tr>
<tr>
<td>Control</td>
<td>-.914, 2.14</td>
<td>-1.19, 2.77</td>
<td>-1.05</td>
</tr>
</tbody>
</table>

*Figure 3.3* The Time Period x Group Assignment interaction demonstrating the relationship between Time and Group is strongest for Weeks 5-10 for the Control Group.
To understand the significant interaction, the groups and time periods were explored using paired-samples \( t \) tests. Weight loss in the feedback group varied significantly between the 0-5 and 5-10 week periods, \( t(14) = -3.1, p < .05, d = 0.92 \), with more weight loss occurring in weeks 0-5 than in weeks 5-10. Weight loss in the control group did not vary significantly between time periods, \( t(13) = .40, p > .05 \). Differences in weight loss during the 0-5 week time period varied significantly between the feedback and control groups, \( t(27) = 1.86, p < .05, d = 0.69 \); however, weight loss differences for the 5-10 week period were not statistically significant between the groups, \( t(27) = -1.2, p > .05 \).

Next, the weight loss for both the feedback and control groups during their first 5-weeks with the Bite Counter were compared. There was no significant difference in weight loss between the feedback group during weeks 0-5, \( (M = -2.56, SD = 2.59) \) and the control group during weeks 5-10, \( (M = -1.19, SD = 2.77) \); \( t(27) = -1.38, p > .05 \).

**Bite Counter Compliant Individuals**

Weekly data were examined to identify individuals who met a minimal compliance standard with using the Bite Counter during their first 5 weeks of use regardless of whether they were in the Bite Counter or Control group. Five-week compliance standards were based on the weekly compliance definitions discussed previously. Individuals were deemed to have met compliance standards if they missed no more than one day per week of monitoring, and collected a minimum of 14 EAs using the
Bite Counter during the same week. Five-week compliance was defined by selecting individuals with no more than 1 non-compliant week after attaining compliance during the first 5-weeks of bite counter use. Using these screening criteria, 23 of the 30 (76.7%) participants were determined to meet compliance standards during their initial 5-weeks with the device. A \( t \)-test comparing the compliant (\( M = -2.22, SD = 2.89 \)) and non-compliant (\( M = -.90, SD = 1.89 \)) groups showed no significant difference between the amount of weight lost between the groups, \( t(27) = -1.14, p > .05 \).

*Research Questions*

*Research Question 1*

This question asked “Did participants stop eating when the Bite Counter alarm sounded?” In order to evaluate this aspect of the Bite Counter, only users who were compliant with the device were used for this analysis (\( n = 23 \)). The total number of eating activities that met or exceeded the alarm setting was counted for each participant over the initial 5-week time period using the Bite Counter. Next, the number of times that the participant stopped eating at within 3 bites after the alarm sounded (alarm value +3 bites) were counted. A percentage of times each participant stopped eating at alarm value was then calculated by using the formula shown in figure 3.4.

\[
\text{Percentage Stopping at Alarm} = \frac{\# \text{ Times Stopped at Alarm (+3 bites)}}{\# \text{ of EA Met or Exceed Alarm}}
\]

*Figure 3.4* Formula for computing percentage of Bite Counter alarm stoppage.
On average, when the alarm activated, participants stopped eating at the alarm value (+3, -0), 69.2% (M=69.2, SD=17) of the time. A graph of these data is presented in Figure 3.3 below.

![Compliant Participant Alarm Usage](image)

Figure 3.5  Bar graph of the data showing when participants stopped eating at the Bite Counter alarm value.

Research Question 2

This question asked “How long does it take for participants to become compliant with using the Bite Counter?” Only individuals completing the study were used in this
analysis. This analysis used the combined user dataset described above representing an individual’s first 5-weeks of Bite Counter usage (n=29). The outlier originally excluded from the analyses was added back into the sample because the analysis evaluates user compliance, not weight loss, thereby yielding a sample size of 30. Compliance data were calculated using weekly compliance definitions previously discussed (6/7 days with 14 EAs). Results indicated that 80% (24/30) of the participants obtained compliance with Bite Counter usage immediately. Additionally, three individuals obtained compliance within week 2 and one individual in week-three. Two individuals were never able to obtain compliance standards with the Bite Counter. Figure 3.4 below shows the compliance-by-week results used for this analysis. A “Y” in the box indicates a week where compliance standards were met. An “N” in the box indicates a week where compliance standards were not met. The green shading indicates participants who were compliant from the start of the study; the yellow shading indicates participants who attained compliance; the red shading indicates participants attained compliance but failed to maintain compliance and purple shading indicates participants who were unable to attain compliance standards.
Research Question 3

This question asked “What percentage of users cannot comply with using the Bite Counter?” The same data from RQ2 (n=30) were examined for participants who were inconsistent with compliance during their first 5-weeks with the Bite Counter. Compliance screening criteria for each week were the same as used in RQ2 (6/7 days with 14 EAs). Non-compliant users were defined as individuals who had more than 1 non-compliant week (multiple relapses) after attaining compliance, or failed to attain compliance. Results indicated that 23.0% (7/30) of users never attained or failed to maintain compliance standards with using the Bite Counter.

ASA 24 Dietary Recall

A dietary probe was planned in order to spot-check participant Bite Counter usage and dietary intake for both feedback and control groups. Participants were cued by email
and provided with a distinct user identification number and password to access the site. Response rates were extremely low; analysis shows that 30/48 (62.5%) attempted the recall, however only 23/48 (48%) were able to complete the task. The ASA 24 was not repeated, and the information collected was not analyzed.
CHAPTER FOUR
DISCUSSION

The primary purpose of the study was to develop and test an experimental diet protocol based on user feedback from the Bite Counter. A secondary purpose was to examine if this protocol would affect meaningful weight loss by device users.

Hypotheses and Research Questions

Weight Loss

The first hypothesis stated that individuals who received Bite Counter feedback for self-monitoring of energy intake would have a larger total weight loss than individuals who did not receive Bite Counter feedback. This hypothesis was marginally supported, in that while the feedback group lost more weight than the control group in the initial 5-weeks of the study, their weight loss was not sustained in the second 5-weeks and the total overall weight loss for both groups did not vary significantly.

The second hypothesis was that when Bite Counter feedback was introduced into the control group, weight loss per week would increase, mirroring the weekly weight loss of the feedback condition participants. This hypothesis was supported, although the magnitude of the weight loss for the control group with the Bite Counter during weeks 5-10, was less than the amount of weight lost by the Bite Counter feedback group during weeks 0-5.
Both groups lost approximately 2 pounds during their initial five weeks in the study, indicating that when committing to any diet an initial weight loss can be expected, as others have found (Mann et al., 2007). During the second 5-week period, the feedback condition users stopped losing weight whereas the control group, now using the Bite Counter was able to sustain their initial weight loss throughout the second 5-week period, indicating that Bite Counter users were able to overcome the effect of time and continue to lose weight.

Both hypotheses are based on the premise that individual energy intake feedback based solely on Bite Counter target values would provide the wearer with enough information that it would lead to weight loss. At the end of the study, 75% of participants reported that using the Bite Counter changed their eating behavior in several ways. Users reported that the device made them more aware of how much they ate, increased their awareness of portion sizes and caused them to eat slower. It is clear that bite-level feedback helps users manage their intake; however its effect is not large enough to serve as the sole feedback element in a dietary protocol.

Self-Monitoring

In current behavior change literature, the terms “compliance” and “adherence” are normally used interchangeably with both terms having the same meaning, namely how well a participant followed instructions. Clarity and readability is better achieved by separating the terms into two distinct aspects of Bite Counter use in a dietary protocol. First, “compliance” will be used to quantify the daily usage of the Bite Counter, that is,
was the device turned on during periods of energy intake and off when eating was complete? A second aspect of this study was whether participants stayed below target daily bite count limits. This segment of the discussion will be discussed as participant “adherence”.

**Compliance with the Bite Counter**

Compliance measured whether or not the user remembered to wear the device, turn it on when they started eating and off when they stopped eating. A minimum level of compliance was operationally defined in order to objectively measure how well participants followed the usage instructions supplied with the Bite Counter. Minimum compliance was defined as using the Bite Counter a minimum of 6 of 7 (86%) days per week and capturing a minimum of 14 EAs during the 7-day evaluation period. This definition of compliance was based on Livingstone’s and Black’s (2003) comparison of reporting biases in several popular energy intake observation methods. They compared observation, weighed records, estimated records, diet history, 24-hour recall and food-frequency questionnaire. Overall, they found that these methods captured 86% of an individual’s energy intake. Translating this to the Bite Counter method, capturing eating data for a minimum of 6 days out of a 7-day week represents an individual’s energy intake at the same accuracy level (86%). Screening also included looking for a minimum number of eating activities per day. (Ma et al., 2003), reported the average number of meals eaten per day was 3.96 \( (SD = 0.8) \). A minimum number of meals per day was extrapolated using this value \( (3.96 - 2.4 \times 3\ SD) = 1.56 \) resulting in the minimum number
of meals eaten per day of approximately two. Therefore an additional screening criterion of 14 eating activities in a 7-day period was established. One additional compliance criterion was compliance over time. A participant could initially be compliant, but then not remain compliant. Hence, one additional criterion was that compliant users could not have more than one non-compliant week after attaining compliance.

*Adherence to the Diet Protocol*

For the purpose of this study, adherence was defined as whether or not a participant stopped eating when reaching a bite target value. Compliant users were examined to determine whether or not they were adherent to the Bite Counter diet. This analysis was performed by examining the Bite Counter log files to determine the number of days that participants actually ate at or below their bite target values ± 10%. Next, these records were evaluated to determine how many of the participants remained under this limit for 5 out of 7 days per week for a five-week period. Of the 20 users who were immediately compliant with the device, 13 users (65%) were found to be adherent to the diet protocol. These adherence measures should be incorporated into future study designs in order to ensure that study participants are following the protocol.

*Research Questions*

Three research questions were included in this study in order to gather preliminary data on several aspects of participant behavior while using the Bite Counter. These questions dealt with how users behaved when the device’s alarm sounded, how
long it took for users to become compliant and finally, what percentage of participants could not use the device.

Research Question 1 asked if participants would stop eating when the Bite Counter alarm sounded. The Bite Counter incorporates an alarm feature that allows the experimenter to set an alarm value at either the meal or daily total bite level. For this study, all participants began with the meal-level alarm set to one-third of their daily bite target value. Alarm values were adjusted as bite target values were titrated during the study. Adherence standards were defined by examining how often participants stopped eating within 3 bites of reaching the pre-determined bite limit. The within 3 bite limitation was arrived at anecdotally based on participant interviews. Most users reported evaluating the portion of food remaining when their alarm sounded. If there were only 2 or 3 bites remaining, they reported finishing their eating activity, whereas if the portion remaining was larger than 2-3 bites most users reported stopping at the alarm. To operationally evaluate this aspect of the Bite Counter participant eating activity logs were evaluated to determine three distinct values: the total number of eating activities for each individual, the number of times their number of bites exceeded their bite target value, and the number of times participants stopped eating within 3 bites of reaching their limit. Participants stopped eating within 3 bites of their alarm on average 69.2% of the time. This indicates that the Bite Counter Alarm has some ability to control eating behavior. Based on anecdotal evidence, similarities in adherence behaviors were segregated into common groups. Participants with greater adherence shared several behavior traits, for example, individuals who wore the device all of the time had announced their intention to
lose weight and had the support of family or friends all had higher adherence rates. Highly adherent users normally wore their Bite Counters all of the time, knew the bite target value and planned their intake based on the number of bites they had remaining for the day. Non-adherent users seldom heard the alarm, or did not stop eating when the alarm sounded.

Research Question 2 asked “How long does it take for participants to become compliant with using the Bite Counter?” This study showed that adopting the Bite Counter was relatively easy for most participants. The majority, 24/30 (80%), of the participants obtained compliance with Bite Counter usage immediately during week-one. Additionally, three individuals obtained compliance within week 2 and one individual in week-3. Two individuals were never able to obtain compliance standards with the Bite Counter. This indicates that future Bite Counter studies can expect users to successfully attain compliance standards during their initial 2-weeks of introduction to the device 90% of the time.

Research Question 3 asked “What percentage of users cannot comply with using the Bite Counter?” Research Question 2 only dealt with obtaining compliance with the Bite Counter. Research Question 3 is based on examining two failure-related aspects of using the Bite Counter, failing to obtain and failing to maintain compliance. This analysis revealed that two participants could never obtain compliance with the device. Additionally, five participants were not able to maintain compliance with the Bite Counter after demonstrating that they could be compliant. There were a total of 7 participants representing 23% (7/30) of the sample who could not obtain or maintain
compliance with using the Bite Counter. Anecdotally, these seven non-compliant participants shared several traits. All 7 did not wear the Bite Counter throughout the day, choosing instead to put the device on right before eating and removing it immediately after eating. They never seemed to know where their Bite Counter was and would often have to dig in their purses to find it or completely forget to bring the device to follow-up appointments. Further, this group described the device as ugly, clunky, and uncomfortable.

*Human Factors Approach*

*Human Factors Analysis of the Data*

As a first attempt at applying Human Factors design principles to the development of the Bite Counter, user personas were established to describe the common positive and negative behavioral traits anecdotally observed during this study. According to Cooper, Reimann, & Cronin, (2012), personas are a gathering of realistic representative information about a group which may include fictitious details to increase the accuracy of the characterization. The persona composition may be based on demographic or biographical characteristics, or the personality or behavioral traits of a group. Personas have names like real people and can be represented through an image, or even a picture, to add realism. They may also be useful in the identification of those who may have trouble with Bite Counter compliance or adherence to a diet protocol based on bite count. User personas can also aid future researchers in the early identification of study participants who may be at a higher risk for dropping out of the study. Ideally, it would
be beneficial to determine performance predictors based on matching the persona to a participant in order to predict problematic or poor performing participants in follow-on studies. Three distinct compliance personas were developed based on the shared behaviors and traits of Bite Counter users: the Committed Cathy (the rapid adopter, seldom misses tracking eating activities), the Reluctant Rita (often forgets device, always has an excuse) and the Negative Nancy (will not wear or use the device). These personas will inform future experimenters on how to improve usage instructions that increase participant compliance with using technology-based energy intake monitoring tools such as the Bite Counter. These personas are described in more detail below.

**Personas**

*The Committed Cathy*

Cathy is excited and cannot wait to get started. She asks questions about the Bite Counter and how she can use it to help her lose weight. During an interview it may be noted that Cathy is knowledgeable about food and calories and has experience with weight loss and dieting. She leaves the office wearing the device and will usually have it on her wrist when she comes in to the lab for follow-up appointments. Cathy will rapidly adopt the Bite Counter, she seldom misses recording an eating activity and she eats a consistent diet (times and amounts similar). Cathy usually stops eating at bite target value or alarm and usually loses weight each week. When Cathy overeats, she does so with the Bite
Counter engaged and can provide the details of why she overate when asked. Cathy is highly motivated and excited about her weight loss success and asks if she can participate in an exercise program to increase her rate of weight loss. Cathy also has the full support of her friends and family, has professed her intention to lose weight to everyone and can often be seen explaining her Bite Counter to anyone who asks about it.

The Reluctant Rita

Rita has experience with weight loss and dieting and claims to be knowledgeable about food. Rita reports that she is ready to lose weight, but struggles with it. During follow-up appointments you note that Rita never has the Bite Counter on her wrist, usually pulling it out of her purse or pocket. She admits that she only puts the device on when she eats, and removes it immediately. Her weight changes vary weekly with weight gains or losses of several pounds interlaced with weeks of no progress. Rita’s diet is not consistent (times and amounts vary widely). She often forgets to wear the Bite Counter, but always has an excuse about why she didn’t use the device. Some weeks Rita appears compliant with instructions, but there is a moderate weight gain (you suspect she is not recording all eating activities). She is quick to offer explanations about the problems that interfere with her ability to follow diet protocol. Often, Rita lacks the support of friends and family or may even report that they sabotage her efforts.
The Negative Nancy

Nancy is an experienced dieter who has struggled with weight loss for years. She knows the diet lingo and professes to have “tried them all”. She is knowledgeable about food, calories and the benefits of exercise. Nancy listens to the Bite Counter explanation, but complains about its size and appearance immediately. When Nancy reports to the lab she has to “dig” the Bite counter out of the bottom of her purse. Her eating activity often shows several consecutive days of no eating activity. Nancy’s eating patterns are not consistent (times and amounts vary widely). Nancy’s weight varies weekly with a weight gain or loss of several pounds. She almost never stops eating at a Bite Target Value or when the alarm sounds. She is excited when she has a successful week, but alibis her conduct when she gains weight. When questioned about her use of the Bite Counter Nancy repeats her criticism about the device’s appearance noting that it is ugly and clunky. Nancy claims that the Bite Counter doesn’t fit her lifestyle (or eating style). During follow-up interviews Nancy admits that she is embarrassed to wear the device because it lets everyone know that she is trying to diet. Nancy also lacks the support of friends and family and has not disclosed her weight concerns or intention to lose weight to anyone. Nancy also wants to talk about her personal problems with you and sometimes cries when she tells you about how her life issues prevented any weight loss since her previous weigh-in.

Figure 4.3 “Negative Nancy”
Weight loss in the Committed Cathy Group

Committed Cathy represents a “best case scenario”. Therefore, a post-hoc analysis of weight loss in this group was performed. Committed Cathy was operationally defined as a user who reached compliance with wearing the Bite Counter (as defined above) and who was adherent with the Bite Counter diet. Adherence to the diet was operationally defined as staying within 10% of the daily target bite count goals on a simple majority (5/7) of days each week. This definition represents a logical “tipping of the scales” if you will, in that assuming our target bite count goal represents a reasonable target for intake, staying near this goal on a majority of the days of the week should place Committed Cathy on a weight loss trajectory. In order to maximize the sample of Committed Cathys, we ignored the group they were in and examined the first 5-weeks of wearing the Bite Counter as the first 5-weeks are available for both control and experimental participants. We identified 13 participants who met an operational definition of Committed Cathy. One of the participants was previously identified as an outlier in the weight loss analysis and was omitted, leaving a total of 12 Committed Cathys. We performed a one sample t-test comparing weight loss change in this group to zero. The mean weight loss for Committed Cathy was 2.37± 2.33 lbs., $t(11)= 3.53, p<0.05$). This weight loss is larger than both the weight loss in the total Bite Counter usage group (feedback group weeks 0-5, plus the control group weeks 5-10, n=29) of 1.90 ± 2.72 lbs. and the large control group (all control participants who completed first 5-weeks) weight loss of 1.72 ± 4.08 lbs. The percentage of alarm usage data from Research Question 1 was re-examined to determine how Committed Cathy used the Bite Counter Alarm. Of the 23 compliant
participants, 13 were classified as a Committed Cathy. Further, 9 of 13 Committed Cathy users had alarm-use percentages at or above the median value and 4 of 12 below the median value. Overall, the development of the Committed Cathy behaviors is critical to maximize a participant’s likelihood of success. Additionally, non-Committed Cathy behaviors should be mitigated early in future studies, or used as a basis for early identification of participants who are more likely to drop out of future studies or will not be successful with the Bite Counter weight loss diet.

**Study Limitations and Future Work**

**Gaps in Design of BC**

The Bite Counter in its current form is a valuable tool and performs its intended function very well, i.e. it counts the number of bites of food the participant placed in their mouth. Additionally, the device provides researchers with the date, time of day, and duration of eating when the device is used as instructed. Several shortcomings exist in the current design of the Bite Counter. They can be grouped into four distinct aspects to aid the discussion: usage (wearing the device), function (counting bites), data (energy density and foods) and purpose (other scientific uses).

First, the Bite Counter must be worn in order to be used. Many users complained that the device was too large, clunky, ugly, not water resistant and uncomfortable to wear. Users requested color options, a smaller footprint and a larger display. These issues should be evaluated during the development of future versions of the Bite Counter. Increasing the comfort and appearance of the Bite Counter would result in an increase in the likelihood that the device would be worn; thereby increasing the chance those users
would count their eating activities. Additionally, wearing the Bite Counter is a formal declaration that the user is participating in a diet program and is intending to lose weight. The negative effect caused by this “stigma” was not examined in this research study. This admission is a reminder of the complex issues that abound in the study of human weight loss behavior.

Second, while counting bites using the Bite Counter participants forget to turn the device on prior to eating, or off when eating is complete, resulting in errors. Automating the on and off function would theoretically ensure that the Bite Counter is capturing all of the participants daily eating activity. For researchers wanting to capture all energy intake events, automation would be beneficial. However, automation could have unintended consequences. Users engage with the device when they turn it on and off. In a way, they are accountable to the Bite Counter for the bites they choose to record. Removing this interaction merits further study of the effect that user interaction with the Bite Counter has on the self-regulation aspect of behavior change.

Third, the Bite Counter counts all foods the same. Energy density varies widely among the foods that make up most diets. Because the Bite Counter counts bites of popcorn the same as it counts bites of M&Ms, researchers and users seem reluctant to trust a dietary protocol based on total numbers of bites. In addition to energy density, some foods such as popcorn often have abnormally high bite counts per serving, possibly due to how the foods are consumed or excess manipulation of food items prior to eating. These differences in foods interfere with the consistency needed in executing a dietary
protocol based on bite count. It is not known how an improvement in accuracy would affect the usage of the Bite Counter.

Lastly, the purpose of the Bite Counter should be examined. There is scientific value in the review of Bite Counter data to examine eating behavior exclusive of what was eaten. Researchers have not exploited this capability to its full extent. Research efforts have focused on using the Bite Counter for weight loss, largely ignoring the value of the device as an objective tool for collecting quantifiable energy intake demographics. There is great value in knowing how many times per day an individual is engaging in an eating activity, its duration and patterns in eating behavior that emerge when the data is reviewed. Exploring this capability of the bite counter has largely remained unstudied. Noticing that a participant recorded an eating activity at 1:00 a.m. on two consecutive Saturday mornings prompted asking a participant if they were in fact eating at that time. The participant responded that she and her friends normally ate fast food after socializing until midnight. This observation prompted a discussion about the effects of eating energy dense foods prior to going to bed. Similar discoveries would aid dieticians and weight loss counselors in the identification of abhorrent or undesired eating behaviors or patterns.

In-Study Performance

Since its inception, the novelty of the Bite Counter led researchers to believe that the device’s simplicity would transcend many behavioral issues common to weight loss such as obeying calorie limits, modifying one’s diet, avoiding foods high in fat or calories
or binge-eating. Clearly, the Bite Counter is not a one-size-fits-all solution. Researchers should actively identify individuals for whom the Bite Counter is not working, and consider dropping them from future studies or recommending an alternate program early-on. This would allow researchers to focus their efforts on developing a viable protocol that targets the participants who are using the device as instructed. Although this could be seen as creating a biased sample, it actually only accelerates the attrition process. Participants who withdraw or quit prior to the end of a study are not represented in the data other than being reported in the attrition rate of a study. Non-completers are not used in computing effect sizes or descriptive statistics therefore their early identification and elimination are not problematic.

Participants should be able to obtain compliance with using the device immediately. Individuals who cannot obtain compliance with the device by the second week should be eliminated from the study. Individuals who fail to lose 2.5% of their starting body weight within 30-days of starting the study should also be considered for elimination. Participants, who routinely ignore bite limits, eat past the alarm, forget to wear the device or ignore other study directives; should be warned that repeating these behaviors are grounds for dismissal from the study.

*Diet, Nutritional Information, Exercise and Counseling*

The current study did not address the dietary content or eating habits of the participants, nor did it provide advice or input on how to incorporate exercise into the weight loss paradigm. All participants were provided with current National Institutes of
Health pamphlets on weight loss, diet and exercise that would normally be available in a doctor’s office. Participants did not receive individual or group counseling. Future study protocols should consider incorporating nutritional or weight loss counseling as well as counseling on the weight-reducing benefits of regular exercise in an effort to increase overall success rates and instill behaviors known to help participants change their behavior permanently.

*Females Only*

Another limitation of the study was the limited generalizability due to the inclusion of only female participants. Participants in this study were recruited primarily from University staff and faculty, instead of from the undergraduate student body. This provided a more diverse population, however many participants were experienced dieters, many of whom have struggled with managing their weight. A majority of participants had numerous unsuccessful weight attempts as opposed to the undergraduate pilot study participants, many of whom were experiencing their first episode of dieting or battling obesity.

*Subject Selection Criteria*

Future studies should attempt to assess an individual’s readiness to lose weight or likelihood of successful behavior change through pre-screening assessments. These predictive elements should be incorporated into the user personas as well. Aggressively screening participants during study uptake may prevent devoting time, tools and energy
to individuals who are likely to drop or withdraw early from the study. The use of a simple 5-question screening questionnaire may prove highly effective at identifying some potentially problematic users prior to enrollment in future studies. Example items for a potential questionnaire are:

1. Which expression would best characterize your diet experience? (“I have tried several”. or “I have tried them all.”)
2. Do your family and friends know that you are dieting?
3. Would you be willing to wear a button every day that says “Ask me about my diet!”?
4. Do you have skin sensitivity issues that would prevent you from wearing a wrist-watch during the day?
5. How many times per week do you eat out?

Although the current literature is conflicting as to which measures are successful predictors, evidence supports employing the Self-Motivation Inventory (SMI) (Dishman & Ickes, 1980) in future studies. The SMI is a general scale measuring perceived confidence to achieve established goals, finish tasks initiated and persevere in spite of difficulties. Clifford et al. (1991) have shown the usefulness of the SMI to predict weight changes, as well as demonstrating a correlation with the SMI and eating restraint, disinhibition and hunger scores after weight loss. Ultimately it would be beneficial to establish representative scores on the SMI for the personas established during this study. This would give future researchers the ability to effectively classify and screen users during study intake instead of after weeks of trial and error.

*Weight Loss Protocol Changes*

Future studies should concentrate on establishing a daily bite target value as soon as possible. Using the current protocol, all participants started with 100 bites per day and
a meal-level alarm value of 33 bites per eating activity (representing one third of their daily total of bites). Bite target values were initially titrated using the flowchart shown in Figure 2-1. Once the study was underway, the review of the previous weeks’ eating activity led to adjustments that were tailored to each individual instead of the broad application of the flowchart. For example, if a participant reported in each week with a 2 pound weight loss, but only averaged 75 bites per day, according to the titration flow-chart, their bite target value would have remained at 100 until they reported for a weigh-in session with a loss of less than 1 pound or a weight gain. Only then would the BTV be adjusted downward while still remaining above their average bites. In this example, the initial 100 bite target value would be adjusted to 75 bites per day once a weekly average bite value was established. Establishing a bite target goal that is believable and supported by the user is critical. The current study found that establishing this value was different for each user. Of the 23 Bite Counter users who attained and maintained compliance, 5 users required 1 adjustment, 9 users required 2 adjustments, 7 required 3 adjustments and 1 user each for 4 and 5 adjustments. Two users were switched from meal level bite count to daily level bite count based on demonstrated eating performance and participant interviews. An algorithm that attempts to determine a custom bite target value for each participant might be beneficial, however an actual bite target based on demonstrated bite count history would still remain the best method for setting new bite goals.

Weekly weight, body measurements at the waist and hips and body fat percentages were collected during this study. Weekly weigh-ins were an important factor during this study. Burke, Wang, & Sevick, (2011) report that frequent self-monitoring of
weight is associated with more successful weight loss and less frequent self-weighing with less successful weight loss or weight gain. However, consistent weekly body measurements and body fat percentage collection proved to be difficult and probably not necessary due to the relatively small changes observed in this study and the lack of compliance with the weekly weigh-ins. The accuracy of the hand-held, capacitance-based, body fat scanner has a large variability, and served as an estimate only. Future studies should consider employing more accurate technology such as the Dual-energy X-ray absorptiometry scan for an initial evaluation of an individual’s body composition paired with a follow-up scan for selected individuals who met weight loss goals.

The ASA24 dietary recall is time consuming and initially difficult for many users. Participants had difficulty completing the ASA24 dietary recall at home during this study. Researchers who need this data should consider building time into study appointments for the user to complete the recalls in-office as opposed to at home. This would ensure that the website would run properly and provide participants with assistance if needed; thereby ensuring the data are collected.

Future studies should also seek to determine how the Bite Counter can be used to change eating behavior, exclusive of measuring weight-loss. For example, future studies should evaluate whether the device is able to teach users how to eat to a target value and stop eating. Demonstrating this capability will ultimately be valuable for use in weight-loss studies and provide valuable insight to changes necessary to the development of future protocols which incorporate the Bite Counter.
Conclusion

In conclusion, the primary purpose of the study was to develop and test an experimental diet protocol based on user feedback from the Bite Counter and to examine if this protocol would affect meaningful weight loss by device users. The protocol evaluated in this study had several significant shortcomings, notably the lack of an aggressive screening criterion for participants and trying to limit weight loss to 1-2 pounds per week. This study did not produce significant weight loss for study participants using the Bite Counter, although the Bite Counter was effective in increasing the amount of weight lost in the short-term and was also able to help the control group users sustain weight loss for a longer period of time, there was no significant weight loss.

Modifications to the Bite Counter diet protocol should result in increasing the likelihood of successful weight loss in future participants. This study also combined the positive and negative behaviors of the participants into three distinct user personas that will aid in the identification of good and poor performers earlier in future studies. The recommendations outlined in this study should inform future research efforts on how to increase the overall effectiveness of the Bite Counter as a tool for fighting the world’s obesity problem.
APPENDICES
APPENDIX A

HOW TO EFFECTIVELY USE A BITE COUNTER

What does the Bite Counter measure?

The Bite Counter counts bites during an eating session. An eating session is defined as a period of eating that has definite start and end times. Some meals can consist of multiple eating sessions. For example, a multi-course meal such as an appetizer, main course and a dessert would define 3 eating sessions where the Bite Counter should be turned on and off after each of the courses of the meal. Basically, an eating session begins after all food is prepared and served and starts on the first bite of that food. The eating session ends after either all of the served food is eaten or a decision has been made to not eat it all and the individual stops eating. Significant pauses during a meal, i.e., for > 1 min, require one eating session to be ended and another one to be started. Grazing on food or drink throughout the day while going about your other daily activities (e.g. working at a computer) is not considered an eating session. The Bite Counter will not accurately measure during grazing. It is important to note that the Bite Counter counts a bite of food and a sip of liquid the same.

The Bite Counter does not count calories; it simply tracks your food intake by monitoring your wrist motion. It also does not know what type of food you are eating so it would count bites of celery the same as it would bites of candy. Our research has shown that the majority of users consistently eat the same number of bites.

Will the Bite Counter work for me?

Are you…

- a person who eats in defined eating sessions, e.g., a person who typically eats meals defined as breakfast, lunch and dinner with or without discreet between meal-snacks?
- a person willing to wear the device continuously or carry it with them constantly in order to have it available to wear during eating?
- a person able to remember to turn the device on just before taking the first bite of food or sip of liquid and turning it off just after taking the last bite of food or liquid?

…then yes, the Bite Counter should work for you!

When am I likely to have problems using the Bite Counter?

If you are…

- a person who grazes, eating more or less continually throughout the day while doing other activities, and never really stops other activities to focus on eating.
- a person who has a high level of hand/wrist tremor (e.g. a person with a nervous system disorder such as Parkinson's disease).
- a person unwilling to wear the device continuously or carry it with them constantly in order to have it available to wear during eating.
- a person unable to remember to turn the device on just before taking the first bite of food or sip of liquid and turning it off just after taking the last bite of food or liquid.

…then the Bite Counter may not work for you.
How to effectively use the Bite Counter to count bites during eating sessions

1) The Bite Counter should be worn on the wrist of the hand that you normally eat with, typically your dominant hand. It is worn like a watch. The Velcro or leather strap should be adjusted so that it fits snugly but comfortably. It should be tight enough that when you twist your wrist back and forth it should not move about on your wrist.

2) The Bite Counter should be worn at all times except when exercising, showering, swimming, sleeping or doing other activities near water (e.g. washing dishes). By wearing the Bite Counter during most of the day, it will be easier for you to remember to turn the Bite Counter on when you are eating. **Warning:** It is VERY important to keep the device dry because it is not waterproof or water resistant.

3) You turn the Bite Counter on after you have prepared all of your food and just before you take your first bite of food or sip of liquid. You turn the Bite Counter off immediately after you have taken your last bite of food or sip of liquid for that eating session. Note there may be multiple eating sessions within a typical meal.
   a) If you notice that you have taken a bite of food or sip of liquid and forgot to turn the Bite Counter on, please turn it on immediately (make a note of it if possible).
   b) If you notice that you forgot to turn the Bite Counter off immediately after you took your last bite of food or sip of liquid, turn it off as soon as you notice (make a note if possible).
   c) If the device inadvertently turns off during an eating session, assuming you are continuing to eat, turn it back on as soon as you notice (make a note if possible).
   d) If the device inadvertently turns on during a time other than an eating session, turn it off as soon as you notice (make a note if possible).
   e) Do NOT turn on/leave on the Bite Counter during food preparation (e.g., cooking, unwrapping food, adding condiments to food before beginning to eat, etc.).
   f) If you take a break from eating in the middle of a meal to prepare additional food, turn the Bite Counter off during the food preparation and then on when you begin eating again. This would be considered 2 eating sessions. Any break in duration of greater than 1 minute warrants stopping the eating session and starting an additional eating session when you are ready to begin eating again.
   g) Once an eating session has begun, it is not necessary to turn the Bite Counter off for any minor food manipulation that normally occurs during eating and lasts only a few seconds in duration (e.g., adding salt or pepper to your meal, cutting food, etc.). However, when you get up from the table to do something that lasts 1 minute or more, like going through a buffet-line, to the bathroom, etc., you should consider that the end of one eating session and turn the Bite Counter off. Then when you sit down again and are about to take your first bite of the next serving of food, consider that the beginning of another eating session and turn the Bite Counter on again.

4) Eat and drink normally while wearing the Bite Counter.

5) The Bite Counter may not work properly if it is not fully charged. You should charge the Bite Counter weekly. Simply plug the device in overnight while you are sleeping.
BITE COUNTER INSTRUCTIONS

Warning: THE DEVICE IS NOT WATER PROOF OR WATER RESISTANT

Participant Instructions for Using the Bite Counter:

1. Place the Bite Counter on your wrist and adjust the tightness using the Velcro or leather band.

2. The default mode for the Bite Counter is “Time” mode. The display will show the time, with an arrow to the left of the screen to indicate PM when appropriate.

3. Once you have prepared all of your food and you are ready to take your first bite, press the left button once. A series of sounds will indicate that the device has turned on. As the device turns on it calibrates the sensor. During calibration it is important to hold the device as still as possible. While calibrating, the display reads “1888”. Once the device has calibrated, the device will be in Bite Count mode and depending on the device settings, the device will now display your active bite count, calorie count or just the word “on” to indicate that it is in Bite Count mode. If the device continues to display “1888” for more than a few seconds, you should turn the device off and back on again.

   This is what the display should look like before you press the left button.

   Press the left button to begin counting bites.

4. Continue to eat and drink normally.

5. Once you have finished and have taken your last bite, press the left button again to turn off Bite Count mode. A series of sounds will indicate that the device has turned off. Your data will save automatically and the display will return to ‘Time’ mode.

   This is what the display should look like after you have activated the bite counter (the number of bites or calories will increment with each bite or the device will simply display the word “on”).

   Press the left button again to deactivate the bite counter.
6. To review the days stored on the device, you use the right button. The device may present all or some of the following: most recent bite count, most recent calorie count, daily total bite count, daily total calorie count and battery status. You access these data from the ‘Time’ mode. Simply press the right button to cycle through the available data. At a minimum you will see the battery status and the time.

7. It is best to charge the Bite Counter every night. The battery status indicator is based on 0-4 scale (in bars, similar to a cell phone). At zero, the device will not enter Bite Count mode in a reliable manner. At 1-4, the device will enter Bite Count mode. However, the length of recording time available will be dependent on your individual eating behavior. In our experience, if the device is charged every evening, the typical user can make it more than one day. Hence, by charging daily if a charging session is missed, you can charge it that evening the next day and still have a functioning device.
   a. To charge the Bite Counter, insert the large end of the USB cable into the power supply and plug the small end of the USB cable into the Bite Counter making sure it goes in the right way.
   b. The display will read “chr” when the battery is charging and will display ‘Time’ mode when charging is complete. When you think the device is fully charged, you should still check the battery status indicator to see that it reads 4.

8. Please wear the Bite Counter at all times during your waking hours except when exercising or entering the water.

Reminder:

THIS DEVICE IS NOT WATER PROOF OR WATER RESISTANT.
APPENDIX C

Clemson Weight Loss Study

1. Information about Being in a Research Study
Clemson University

The Bite Counter as a Behavioral Intervention for Weight Loss

Description of the Study and Your Part in It

Dr. Eric Muth is inviting you to take part in a research study. Dr. Muth is a Professor of Psychology at Clemson University. The purpose of this research is to evaluate wrist-worn devices as tools to assist with individual weight loss. Dr. Muth is one of the co-inventors of the Bite Counter and an officer in Bite Technologies, a company selling the Bite Counter.

Your part in the study will be to:
• complete a short form about yourself
• have your height, weight, body composition, waist and hips measured
• complete an on-line diet interview one time per week to report what you ate during the previous day
• wear a wrist-worn watch-like device during meals and throughout the day and using the feedback from the device to reduce your eating with the goal of losing 1-2 lbs per week
• complete weekly progress interviews about your compliance with the study protocol in order to just your bite count goal to maintain 1-2 lbs per week weight loss

It will take you 15 consecutive weeks to complete this study. Weekly meetings will be conducted to evaluate your weight loss progress. Feedback from the wrist-worn device will be used to adjust your bite count to maintain weight loss to approximately 1-2 lbs per week. These weekly meetings will require approximately 15 minutes to complete.

Please maintain good care of the Bite Counter. At the completion of the study you will be required to return the Bite Counter so that it can be used for future research. If for some reason, you lose or otherwise damage the Bite Counter, your continued participation in the study may be terminated.

Risks and Discomforts

There are certain risks or discomforts associated with this research. They include
Clemson Weight Loss Study

increasing sensitivity to food intake during the day. For this reason, individuals with current or previous eating disorders are asked not to participate in this study.

Possible Benefits

You may lose 1-2 pounds per week as a result of participating in this study.

You may be compensated up to $25 for participating in the study.

Protection of Privacy and Confidentiality

We will do everything we can to protect your privacy and confidentiality. We will not tell anybody outside of the research team that you were in this study or what information we collected about you in particular. Your identity will not be revealed in any publications that might result from this study.

We might be required to share the information we collect from you with the Clemson University Office of Research Compliance and the federal Office for Human Research Protections. If this happens, the information would only be used to find out if we ran this study properly and protected your rights in the study.

Choosing to Be in the Study

You do not have to be in this study. You may choose not to take part and you may choose to stop taking part at any time. You will not be punished in any way if you decide not to be in the study or to stop taking part in the study.

If you choose to stop taking part in this study, the information you have already provided will be used in a confidential manner.

Termination of Participation by the Investigator

The wear and use of the wrist worn device is critical to the success of this study. Termination of your participation may occur from a repeated failure to use, loss of, or damage to the wrist-worn device.

Contact Information
Clemson Weight Loss Study

If you have any questions or concerns about this study or if any problems arise, please contact Dr. Eric Muth, at Clemson University at 864-656-6741.

If you have any questions or concerns about your rights in this research study, please contact the Clemson University Office of Research Compliance (ORC) at 864-656-6460 or irb@clemson.edu. If you are outside of the Upstate South Carolina area, please us

☐ Yes, I give my consent.
☐ No, I do not give my consent.

* 2. Please enter your unique participant ID provided by the experimenter. (Will be in format: WLS###. If you do not remember your participant ID, please check your email messages. If you deleted your participant ID, e-mail cuw1study@gmail.com if you have forgotten your ID.)

* 3. What is your preferred contact email address?

Please complete all questions below as accurately as possible.

* 4. What is your age in years?

Years

* 5. What is your gender?

☐ Male
☐ Female
Clemson Weight Loss Study

6. What is your ethnicity?
- American Indian or Alaska Native
- Asian or Pacific Islander
- African American
- Caucasian
- Hispanic
- Indian
- Other (please specify)

7. Have you ever been diagnosed with an eating disorder (e.g., Anorexia, Bulimia)?
- Yes
- No

8. What is your height in feet and inches?
   Feet: 
   Inches: 

9. What is your weight in pounds?
   Pounds: 

10. What is your goal weight in pounds?
    Pounds: 

11. Are you currently following a specific diet, or way of eating? (vegetarian, vegan, gluten-free, other)
- Yes
- No
- If yes, please describe your diet:

12. The best day for us to meet is:
- Monday
- Wednesday
- Friday
13. The best time for us to meet is:

- 8 a.m.
- 9 a.m.
- 10 a.m.
- 11 a.m.
- 12 p.m.
- 1 p.m.
- 2 p.m.
- 3 p.m.
- 4 p.m.
- 5 p.m.
- After 5 p.m.
The Bite Counter as a Behavioral Intervention for Weight Loss

Researcher Protocol - Recruitment

1. Recruit participants with flyers, advertisements and word of mouth.
2. Perform screening using an initial survey and a follow-up interview.
3. After being contacted by a potential recruit assign a unique participant number and respond with the following e-mail (protocol assumes survey already exists at SurveyMonkey.com):

   Dear Participant,

   Thank you for expressing interest in our study. Your acceptance into our study is determined by your responses to the survey below. If accepted, your participation involves two parts. Part 1 involves a short interview, some body measurements including height, weight and Body Mass Index (BMI), familiarization with the Bite Counter device. Part 2 includes weekly follow-up meetings to check your weight-loss progress. During this review we will check your weight, repeat your body measurements and the previous weeks Bite Counter data. Your daily bite count goals will be adjusted to maintain a safe and healthy weight-loss. The study runs for a total of 12 weeks; the initial meeting and 11 short follow-up visits.

   To begin, please complete the survey at the following link:

   https://www.surveymonkey.com/s/PJJMCLN

   Your UserID is: WLS### (where ### = 050-099)

   Thank you again for your interest.

   Sincerely,
   (experimenter)

4. Determine if the participant meets the screening criteria by:

   a. Browse to www.surveymonkey.com (UID: muthlab, PW: L@bGroup!).
   b. Select “My Surveys” at the top sub-menu. Select “Bite Counter Weight Loss Study 1”
   c. Select the “Analyze Results” tab
   d. Select “Browse Responses” from the list at the left
   e. Note the participant number from the responses on Page 2
   f. Move to page 3 and note the response to question 6; If “Yes” then the participant is not eligible to participate.
   g. Use the responses to questions 7 & 8 to verify BMI of ≥ 30 with the table below:
5. If the participant is **ineligible** to participate in the study, respond with the following e-mail:

   Dear (name),

   We appreciate your interest in our study. However, due to the nature of the study, we have fairly strenuous inclusion criteria, and your survey responses have indicated that you are ineligible for this study. If you have any other questions, feel free to contact Mike Wilson at mlw2@g.clemson.edu.

   Sincerely,
   (experimenter)

6. The pre-screening questionnaire will have scheduling options for each participant. Ensure that participants have selected an available time. Schedule the participant and send the following email:

   Dear Participant,

   Thanks again for agreeing to participate in our study. I have scheduled you for (date, time). Please confirm that this time works for you; if it doesn’t, please suggest an alternate date and time. We will be meeting in Brackett Hall, room 422. Your height and weight will be checked and body measurements taken. Please wear or bring clothing such as shorts, t-shirt and socks for your weigh in.

   Sincerely,
   (experimenter)
Researcher Protocol - Initial In-Lab Session

1. 24 hours before each participant is scheduled to have their weigh-in session, send them the following e-mail:

   Dear Participant,

   This is a reminder for your participation in the Bite Counter Weight Loss Study. You are scheduled for tomorrow (date) at (time). We will be meeting in Brackett Hall, Room 422. Remember, your height and weight will be checked, please wear or bring light clothing such as shorts, t-shirt and socks for your weigh in.

   Thank you,
   (experimenter)

2. Greet the participant
3. Upon the participant’s arrival, introduce yourself and thank them again for their participation.
4. Give them the consent form, and instruct them to read it, initial each page and sign and date the last page of the form.
5. Once the participant has finished reading and signing the consent form begin the body measurements.
6. Measure height using the height (to the nearest ¼ inch) and weight (to the nearest ½ pound) using the Tanita WB-3000 scale. Record all measurements on the Participant Note Sheet. To take the measurements, perform the following:

   NOTE: Take all height and weight measurements with participant in stocking or bare feet.

   a. Power on the device, and wait for it to start up and zero itself.
   b. Extend the stadiometer so that it is above the participant’s head.
   c. Ask the participant to step onto the scale with their back to the stadiometer.
   d. Level the stadiometer with the participant’s head, and record height and weight.
   e. Measure height to the nearest quarter inch.
7. Measure the participant’s body fat percentage using the Omron HBF-306 Fat Loss Monitor.

   a. Turn the device on.
   b. Press “set” twice.
   c. Adjust each parameter to that of the participant. Press “set” after each one to move it to the next.
   d. Instruct the participant to hold the device out in front of them with their arms straight and with the feet shoulder width apart.
   e. Record BMI and Body fat percentage.
8. Measure and record the participant’s waist and hip measurements (to the nearest ¼ inch) using the MyoTape device. To use the MyoTape, extend the tape around the participant, latching the end of the tape back into the base. Press the button to retract excess tape and record the measurement that appears on the left edge of the MyoTape. (If possible have a female assistant measure female participants. If none are present, or if the participant prefers, they may measure themselves).

   a. Using the measuring tape, measure the waist at the smallest point near the navel.
   b. Measure the hips around the buttocks.
   c. Record the values on the worksheet in the participant folder.

9. Program the Bite Counter do the following (should be performed prior to arrival of participant).

   a. To set parameters, select “Device” and then select “Set the Parameters”. Once you do this a pop up window with radio button controls. The parameters you can set fall under three categories: “Live Display”, “Review Display” and “Alarm”
      1) Live Display: This controls what is displayed with the device is in “Bite Count” mode. Select “Bites” (note: Only one of the three radio buttons can be active).
      2) Review Display: This controls what stored information the user can cycle through on the device when the device is in “Time” mode. Activating the radio button means that it will be included in the display. Select the radio buttons for Time, Bites, and Bites/day.
      3) Alarm: Select the “Session” radio button. Ensure that “30” is entered into the bites window.
      4) Click “Ok”.

   b. Disconnect the Bite Counter

10. Issue the participant a Bite Counter.

11. Instruct the participant on the use of the Bite Counter using the Bite Counter Instructions document (Appendix B).

12. The Bite Counter diet is based on setting a total daily bite limit for each participant. All participants will begin with a daily bite limit of 100 bites per day.

13. Schedule follow-up sessions with the participant.
Researcher Protocol - Follow-Up Sessions

1. The day prior to the appointment, send the following reminder email to the participant:

   Dear Participant,

   I am sending you this e-mail to remind you of your participation in the Bite Counter Weight Loss Study. You are scheduled for tomorrow (date) at (time). We will be meeting in Brackett Hall, Room 422. Remember that your height and weight will be checked, please wear or bring clothing similar to what you wore in your initial weigh-in.

   Thank you,
   (experimenter)

2. Greet the participant and repeat the weight, body fat percentage, BMI and body measurements using the following procedure:
   a. Measure weight (to the nearest ½ pound) using the Tanita WB-3000 scale. Record all measurements on the Participant Note Sheet. To take the measurements, perform the following:

      NOTE: Take all height and weight measurements with participant in stocking or bare feet.

   b. Measure the participant’s BMI and body fat percentage using the Omron HBF-306 Fat Loss Monitor.

      1) Turn the device on.
      2) Press set twice.
      3) Adjust each parameter to that of the participant. Press set after each one to move it to the next.
      4) Instruct the participant to hold the device out in front of them with their arms straight and with the feet shoulder width apart.
      5) Record BMI and Body fat percentage.

3. Measure and record the participant’s waist and hip measurements (to the nearest ¼ inch) using the MyoTape device. To use the MyoTape, extend the tape around the participant, latching the end of the tape back into the base. Press the button to retract excess tape and record the measurement that appears on the left edge of the MyoTape. (If possible have a female assistant measure the female participant. If none are present, or if the participant prefers, they may measure themselves).

   a. Using the measuring tape, measure the waist at the smallest point near the navel.
   b. Measure the hips around the buttocks.
   c. Record the values on the worksheet in the participant folder.

4. Download the Bite Counter data using the instructions in TAB A.

5. Examine the previous week’s eating behavior using the calendar mode of the Bite Counter software.

   a. Connect the Bite Counter to the computer.
   b. Run the Bite Counter Software.
c. Select “Device” and the “Connect”.

d. Select “View”, then “Calendar”.

6. The first goal is to determine compliance with using the Bite Counter. To determine compliance in using the Bite Counter, perform both steps below:

   a. First, examine the data to flag suspected non-compliance days. There can only be 1 day per week with no eating activities captured.

   b. Additionally, define compliance as using the Bite Counter to capture at least 75% of all eating activities. Based on previous research, the average meals/day value is 3.9, yielding the average total available meals for a week as 27. The participant should have used the Bite counter for a minimum of 20 of the 27 (74%) available meals. This threshold is only valid as a screening tool. If your participant shows a daily eating activity history of 2 meals per day, a weekly total of 10 eating activities may indeed be compliant with the 75% goal.

   c. Non-compliance is grounds for dismissal from the study. If repeated weeks of non-compliance are an issue, discuss the participant with the Principal Investigator.

7. The second goal is to determine if there was a weight loss (the goal is a weekly weight loss of 1 to 2 pounds). Based on the participant’s weight loss, either leave the bite count target the same, lower the daily bite count target, or raise the daily bite count target. To calculate the new bite count target value perform the following:

   a. If compliant and weight loss is 0 pounds, or there is a weight gain, lower the daily bite count target amount by 10 bites and adjust alarm value to approximately 1/3 of the daily total.

   b. If compliant and weekly weight loss is less than 1 pound, lower the daily bite count target amount by 5 bites and adjust alarm value to approximately 1/3 of the daily total.

   c. If compliant and weekly weight loss is less more than 2 pound, raise the daily bite count target amount by 5 bites and adjust alarm value to approximately 1/3 of the daily total. Record new bite count target on the worksheet in the participant’s folder.

8. Schedule the next follow-up session if needed.
TAB A

Instructions for Using the Application Software

a. Before using the Application Software you must first install the Device Driver. The Device Driver can be found at: http://www.icountbites.com/support.html. First download the Device Driver. Then open the directory in which the Device Driver has been downloaded. Now double click on the Device Driver icon. Then follow the instructions that appear on the screen. Note the Device Driver only has to be downloaded and installed once on any computer that runs the Application Software.

b. The latest Application Software can be downloaded from: http://www.icountbites.com/support.html. When downloading new software, be sure to archive or delete the older software to avoid mixing versions. The download is an executable file and it is all you need to interact with your Bite Counter.

c. Plug your Bite Counter into a USB port. Then double click on the Application Software icon. The software will open. You will see a menus system with: “File”; “USB”; “Device” and “Advanced”. The majority of your interaction with the device will occur under the “Device” menu. You will also see a window that provides information on the current status and setting of the device. The all of these status indicators will read “Not connected” until you connect the device using the software.

d. To connect the device, select “Device” and then “Connect”. The status of the device will be updated and any records on the device will be displayed below the status indicator area. In addition, a bar graph will show the total number of bites taken each day that the device was used since the last reset.

e. All of the data that is stored on the device should now be visible. Please note that the device continues to store data until the device’s memory is cleared. However, the “real-time” user review on
the device itself only permits the user to review the last day’s data. The following is a description of the visible data on the device:

1. The computer time.

2. The device time. A and B are shown to ensure that the time on the device matches the actual time. Note that the clock on the device is fairly accurate, but should be synced with the computer time frequently (at least once a week) to make correlating data streams easier (explained below).

3. The total number of records (eating sessions) on the device.

4. The current mode of the device (bites, calories, or “on”).

5. The current calories per bite ratio

6. Alarm mode (day, session, or off).

7. The number of bites that can be taken before activating the alarm.

8. Each record on the device: Date, time that it began recording, the duration of the record, and the number of bites for the record.

9. The total number of bites for a specific day.

10. The current review displays cycled through when pressing the right button on the device.
f. Under the “Device” menu, you can also “Sync time with Computer”, “Clear Data”, “Disconnect”
the device and “Set the Parameters” of the device.

1. Disconnect: This safely disconnects the device from the computer. This function should
be performed prior to disconnecting the device from the computer.
2. Sync time with Computer: This simply syncs the computer clock and the device clock.
   This should be done every time to device is connected to the computer.
3. Set parameters: This allows you to change many of the options on the device (see
   section 7).
4. Clear Data: This clears all of the data from the device. When you attempt to clear the
data it will ask if you have saved the data. You have to attempt to clear the data twice
before it actually clears. This is a safeguard against accidentally clearing the data.


![Device menu screenshot]

An image showing the device menu with options such as Disconnect, Sync time with computer, Set parameters, and Clear data.

To set parameters, select “Device” and then select “Set the Parameters”. Once you do this a pop
up window with radio button controls. The parameters you can set fall under three categories:
“Live Display”, “Review Display” and “Alarm”

1. Live Display: This controls what is displayed with the device is in “Bite Count” mode.
   There are three possibilities: display bites, calories or just the indicator that the device is
   in Bite Count mode by displaying the word “on”. Only one of the three radio buttons can
   be active.
2. Review Display: This controls what stored information the user can cycle through on the
device when the device is in “Time” mode. Activating the radio button means that it will
be included in the display. We recommend at a minimum that Time and Charge be
displayed.
   i. Note that the “Calories” display is controlled by the cals/bite calculation. For
      example, if the cals/bite is set at 20, each time a bite is taken the calorie display
      will advance by 20 calories. If calories are displayed, we recommend that this
      number be based on an individual calculation using some type of food record
coupled with the device during at least a 3 day period.
3. Alarm: this controls whether an alarm is set or not. There are three possibilities: Off; Daily;
   and Session. The alarm is an intermittent beep that goes off with each bite taken
after the alarm threshold has been crossed. Note that once an alarm is activated, the
alarm will go off with each successive bite taken. It is not reset until the next session or
day depending on whether a session or daily alarm is set.


i. Off: No alarm will be activated

ii. Daily: The alarm will be activated after a total number of bites are exceeded for the daily bite count. The alarm resets each day at midnight. A day is defined as midnight through 11:59 pm.

iii. Session: The alarm will be activated after a total number of bites are exceeded for a single eating session. The alarm resets for each eating session. An eating session is defined as the time between the device being turned on and then off.

4. Calories per Bite ratio: this allows you to set the calories per bite conversion ratio.

h. The “Advanced” menu allows you to control two technical features of the device:

1. Update Device App: This allows you to perform a “firmware” update using the “Update Device App Code”. However, you should only attempt a firmware update if you have been instructed by Bite Technologies to do so. Clicking this option will bring up a navigation panel where you should select the device firmware file. Your device shipped with the most recent firmware at that time. If for some reason you are instructed by Bite Technologies to update your firmware, you will find the latest version at: http://www.icountbites.com/support.html.

2. Slow USB connection: If you are having trouble communicating with the device, choose this option and try again.
i. To save the data on the device to the computer hard drive, click on “File” and then “Save Data As”. This will open a dialogue box for saving the data.

![Bite Counter software interface](image)

j. To exit the software click on “File” and then “Quit”. Note that prior to quitting the software you should “Disconnect” the device from the software before exiting the software by clicking on “Device” and then “Disconnect”.

1. Note that the device can be connected to a USB purposes for charging without being connected to the software.

k. There are two new data viewing options available to the user. Data may be viewed in the calendar mode to help determine eating patterns.

1. To view the calendar click on “View” and then “Calendar”.

![Bite Counter calendar view](image)

2. This will open the calendar view to the default screen shown below:

![Calendar view](image)
3. In this view the time of day and amount eaten are pictorially correct in the calendar box for each day. Examine the data for August 13th and 14th; you will notice that the date box for the 13th contains three horizontal bars indicating that three meals were eaten. Also, the bar for the lunch meal is three times as long as the early meal, and about a third longer than the evening meal. This would indicate that the wearer ate a small meal for breakfast, a large meal for lunch and a smaller meal for dinner. Similarly, the data for the 14 shows a breakfast and lunch meal of approximately the same number of bites.

4. Double-clicking on the specific day shifts the software into a detailed bite mode showing the number of bites per day and the times and bite counts for each meal.
Usability Questionnaire

1. Please enter your unique participant ID provided by the researcher. (If you do not remember your participant ID, please e-mail cuwlstudy@gmail.com or call 864-656-1144 to receive your ID.)

______________________________

2. While using the Bite Counter, how full have you felt?

☐ Not full at all                      ☐ Somewhat full
☐ Moderately full                    ☐ Very full
☐ Extremely full

3. How often did you wear the Bite Counter? (Select the option that most applies.)

☐ All day everyday (from morning to evening)
☐ Only part of the day (more often than just meal times)
☐ Only during meal times, the other times I took it off
☐ I did not wear it during some meals
☐ I did not wear it during many meals
☐ I did not wear it for one or more days

4. How easy or difficult did you find it to use the Bite Counter?

☐ Very easy                          ☐ Somewhat difficult
☐ Somewhat easy                      ☐ Very difficult
☐ Neither easy nor difficult         ☐ Extremely difficult
5. What about the Bite Counter made it easy or difficult to use?

________________________________________________________________________

6. How much did you like or dislike using the Bite Counter?

☐ Extremely liked
☐ Liked somewhat
☐ Disliked somewhat
☐ Extremely disliked
☐ Liked very much
☐ Neither liked nor disliked
☐ Disliked very much

________________________________________________________________________

7. What did you like or dislike about using the Bite Counter?

________________________________________________________________________

8. Did you have any problems wearing the Bite Counter due to physical discomfort or other reasons?

☐ Yes
☐ No

________________________________________________________________________

9. What could be done to make it easier to wear the Bite Counter for longer periods of time?

________________________________________________________________________

________________________________________________________________________

10. Did you have any problems using the Bite Counter?

☐ Yes
☐ No
11. Please describe any problems you had with the Bite Counter.

_____________________________________________________________________

12. Did you feel that using the Bite Counter changed your eating behavior?

☐ Yes

☐ No

13. How did you feel the Bite Counter changed your eating behavior?

_____________________________________________________________________

14. Which did you prefer using, the 24 hour dietary recall or the Bite Counter?

☐ 24 hour dietary recall

☐ Bite Counter

_____________________________________________________________________

15. Why did you choose the 24 hour dietary recall or the Bite Counter as your preferred tool?

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________
REFERENCES


