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Evaluating a Novel Device for Calorie Reduction: The Bite Counter Study

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EVALUATING A NOVEL DEVICE FOR CALORIE REDUCTION: THE BITE
COUNTER STUDY

BY

GREGORY G MAYETTE

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE

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MASTER OF SCIENCE THESIS

OF

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Abstract

Background: Self-monitoring dietary intake is a valuable behavior for those wishing to lose weight. Unfortunately, keeping food logs to determine kilocalorie (kcal) intake becomes very cumbersome and, this behavior change is rarely maintained. Although advances in technology have eased the burden of monitoring kcal intake, attrition remains a problem. The Bite Counter is a device worn on the wrist that uses bite count as a proxy for kcal intake, without the need for laborious food intake record keeping. The Bite Counter's efficacy in helping individuals decrease kcal intake by decreasing bite counts in free-living environments has not been tested.

Objective: The objective of this pilot study was to determine if overweight and obese adults could decrease their kcal intake by adhering to a daily bite count goal over one week. Appetite, satiety, and thirst were also evaluated to determine if decreasing bite count would alter these factors.

Methods: This study used a within-subject, pre-post design. The study included adults age 18-48 years old with a body mass index (BMI) between 25 and 39 kg/m². Subjects (n = 19) participated in a two week intervention. During week 1, demographic and anthropometric data were collected, along with baseline kcal intake using 24-hour recalls and appetite profiles using visual analogue scales (VAS). Subjects wore the Bite Counter during the second week, while data collection from week 1 was repeated. A 10-12% bite count reduction goal was established after wearing it for one full day. Kcal intake and appetite profile data were assessed using paired t tests and repeated measures ANOVA. Independent t tests were used to assess between group differences according to bite count goal achievement.

Results: No significant differences were observed in kcal intake between the two weeks. When grouped according to bite count goal achievement, those reaching their goal on average decreased their kcal intake more than those who did not, though this decrease was not significant ($p = 0.064$).

Conclusion: This pilot study underscored the importance of bite goal achievement in reducing kcal intake. Future work should include larger groups, and longer interventions.

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PREFACE

This thesis was written to comply with the University of Rhode Island graduate school Manuscript Thesis Format. This manuscript has been written in a form suitable for publication in the journal *Eating Behaviors*.

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Evaluating a Novel Device for Calorie Reduction: The Bite Counter Study

Manuscript prepared for submission to the journal Eating Behaviors

Gregory Mayette, Geoffrey Greene, Bryan Blissmer, Kathleen Melanson

Manuscript Abstract

Abstract

Background: Monitoring kilocalorie (kcal) intake is pivotal for weight loss, but is cumbersome and rarely maintained. The Bite Counter is worn on the wrist and uses bite count as a proxy for kcal intake. Its efficacy in helping individuals decrease kcal intake in free-living environments has not been tested.

Objective: To determine if overweight and obese adults could decrease their kcal intake by adhering to a daily bite count goal. Appetite, satiety, and thirst were also evaluated to determine if decreasing bite count altered them.

Methods: Using a within-subject, pre-post design, $n = 19$ adults age 18-48 years old, body mass index between 25 and 39 kg/m^2 , participated in a two-week intervention. During week 1, demographic and anthropometric data were collected, along with baseline kcal intake using 24-hour recalls and appetite profiles using visual analogue scales (VAS). Subjects wore the Bite Counter during the second week, while data collection from week 1 was repeated. A 10-12% bite count reduction goal was established after wearing it for one full day. Kcal intake and appetite profile data were assessed using paired t tests. Independent t tests were used to assess between group differences according to bite count goal achievement.

Results: When grouped according to bite count goal achievement, those reaching their goal on average decreased kcal intake more than those who did not, though not significantly ($p = 0.064$).

Conclusion: This study underscored the importance of bite goal achievement in reducing kcal intake. Future work should include larger groups, and longer interventions.

1. Introduction

Obesity is a global health problem associated with increased risk for some of the leading causes of preventable death including cardiovascular diseases, stroke, type II diabetes, and some cancers (1). Currently, over 2/3 of U.S. adults are overweight or obese (2). These individuals experience higher inpatient healthcare costs, spend more on prescription drugs, and have more physician visits than their normal-weight counterparts (3) Finding effective ways to manage weight is critical in addressing these issues.

Weight-loss intervention studies have demonstrated that self-monitoring dietary intake plays a pivotal role in weight management (4-6). Using a paper diary to record food intake and determine kilocalories (kcal) consumed, though quite helpful, can become very labor-intensive, with attrition often resulting (7, 8). Technological advances have eased this burden, some. Researchers have used personal digital assistants (PDA) (9, 10), smartphone applications (11, 12), and food photography (13-16) as alternatives to paper diaries. Though these methods have potential and can lighten the workload of monitoring dietary intake, attrition can remain a problem with long-term use (10, 17, 18).

Other recent technological advances have focused on self-monitoring certain within-meal eating behaviors to help users lose weight without cumbersome food intake recording. A group from Clemson University created the Bite Counter, a wrist-worn device that counts bites of food taken during a meal using a built-in gyroscope to detect wrist roll (19). The Bite Counter counts and time stamps bites from each eating session (19). This information is stored on the device and can be viewed and

uploaded to a computer using accompanying software (19). The software allows users to view bite count logs to help them create future goals, and toggle various device display options, including most recent bite count, total daily bite count, as well as most recent kcal and daily kcal counts (20). Users can also turn on an alarm on the Bite Counter to alert them when a certain bite count number is reached (20).

Initial Bite Counter accuracy tests found the device to be 86% accurate in free-living settings (19). Feasibility research found that 74% of participants preferred using the Bite Counter over other dietary intake recording methods, and that the device could save people an average of 25 minutes daily in estimating and recording kcals (21). A recent laboratory study demonstrated that reducing bite rate using the Bite Counter decreased energy intake, especially among those eating larger amounts of kcals (22). In free-living settings, the Bite Counter was used to demonstrate the existence of a positive correlation between bite count and kcal intake (21). The Bite Counter has also been used as a potential kcal estimation tool when nutrition information was not available (23). No studies thus far, however, have examined the potential for this device to help individuals decrease kcal intake in free-living settings. The purpose of this study is two-fold: 1) -to examine the efficacy of the Bite Counter to help individuals decrease kcal intake by decreasing daily bite count, and 2) -to examine how decreasing bite count affects appetite, satiety, and thirst.

We hypothesize that, compared to a week without the Bite Counter, subjects wearing the Bite Counter for one week in free-living conditions will reduce their kcal intake if they meet their daily bite count goal on average. We also hypothesize that reducing bite count will not lead to increased hunger or appetite, or decreased satiety.

Based on previous research, we also hypothesize a positive linear correlation between kcal intake and bite count within our sample. This study will serve as a pilot study for a future long-term weight-loss intervention with the Bite Counter.

2. Methods

2.1 Subjects

Recruitment took place at the University of Rhode Island and surrounding community using flyers and word-of-mouth advertising with rolling enrollment. Eligible participants were non-smoking adults age 18-48 years, with a body mass index (BMI) >25 - ≤ 40 kg/m². Exclusion criteria included pregnant or lactating women, those with chronic diseases such as diabetes, kidney or liver disease, those taking medications that may alter appetite or energy expenditure, those with documented eating disorders, and those who do not eat in defined meal times (breakfast, lunch, dinner), i.e. “grazers.” Based on previous work in our lab using similar methodology, we expected a completion rate of 90% (24).

2.2 Procedure:

This study was approved by the Institutional Review Board (IRB) of the University of Rhode Island (URI). A within subject, pre-post design with subjects acting as their own controls was used in our intervention. Data were collected from each participant over the course of approximately two weeks with three visits to the lab. The first visit was for baseline data collection, and the other two visits were for repeated study outcome collection following the control week and intervention week.

Females were scheduled to begin the study during the mid-follicular phase of their menstrual cycle, to control for potential cycle-related variability in appetite (25).

Participants initially completed a screening over the phone to ensure they meet the inclusion/exclusion criteria for the study. If these criteria were met, an initial lab visit was scheduled. During this first visit, subjects completed a second screening form similar to the one completed over the phone to verify these criteria. They answered demographic questions, including those inquiring about race, ethnicity, and questions about eating behaviors, including eating rate and meals and snacks consumed per day. If criteria were met, measurements of height (to 0.1 cm) on a freestanding stadiometer (SECA North America, Chino, CA) and weight, (to 0.1 kg) on a digital scale (Healthometer, McCook, IL) were taken to verify BMI criteria were met.

Eligible participants signed an informed consent form explaining the research protocol. Waist circumference and body fat percentage measurements were then taken using a Gulick measuring tape (North Coast Medical, Bolingbrook, IL) to the nearest 0.1 cm, and- by air displacement plethysmography (BodPod;Life Measurement Instruments, Concord, CA), following standardized procedures (26), respectively. They were given a portion size estimation booklet to help them complete two, unannounced 24-hour dietary recalls by phone within the first week to provide a baseline kcal intake average. Subjects were also provided with daily appetite profile visual analogue scales (VAS) -to complete each day of the week upon awaking and before going to bed to assess overall hunger, satiety, desire to eat, and thirst (27).

Finally, participants were given instructions to prepare for completing a test lunch meal on the second visit, to take place one week after this first visit.

During a second lab visit 1 week later, a third 24-hour dietary recall was conducted in person, and VAS data were collected. Participants were then given a Bite Counter to wear for eight days. This allowed subjects the remainder of that day, and the following day to get acclimated with the device before data recording began. They were instructed to wear the device on their dominant hand each day from the time they awoke until bedtime. Subjects were provided with instructions on using the device properly, along with a bite count log/goal setting sheet. This sheet explained how to determine a daily bite count goal based on how many bites they take during their first full day of device use. This daily bite count goal was approximately 10% - 12% fewer bites than the number taken on the first day. For example, if a participant took 100 bites on this first day, s/he would set a goal of 88 bites for the remainder of the week. After adhering to this initial goal on the second day, if they felt the goal was too easy or hard to meet, they could adjust it as they felt necessary. Subjects recorded their bite count goal at the beginning of the day, and their actual daily bite count displayed on the bite counter at the end of the day on a bite count log sheet. Prior to the final visit, subjects completed two more unannounced 24 dietary recalls over the phone during this second week. Participants completed a final in-person 24-hour dietary recall and received a \$100 stipend upon completing the study.

2.3 Analyses

Total daily bite counts were recorded by subjects on their log sheet, and also by the Bite Counter itself. Software provided by Bite Technologies, the company supplying the devices for this study, was used to extract these data from the Bite Counter during lab visit 3 when the device was returned to the lab. Average daily bite count and average bite count goal attainment during the intervention week were determined for use in analyses. These averages were calculated based on the data available, which varied for each subject. Data obtained from all 24-hour dietary recalls were analyzed using Food Processor SQL 10.1 to determine kcal intake. An average kcal intake over the three days was determined for each participant for both the baseline week and the week with the Bite Counter. Kcals-per-bite were calculated by dividing average kcal intake from the intervention week by average daily self-reported bite count. Before breakfast and bedtime VAS data were averaged from both weeks. Mean kcal and VAS data from the baseline week were compared with data from the intervention week using two-tailed paired t-tests and repeated measures ANOVA. Independent t-tests were used to examine these data between subjects meeting their bite count goal, and those who did not. Pearson correlations were used to examine bite count and kcal relationships. All kcal and VAS data were assessed for normality using Shapiro-Wilk tests. Box plots were used to determine outliers of ± 3 standard deviations from the mean. Data are mean $\pm$ standard deviation, unless otherwise noted. Statistical analysis was completed using SPSS version 22.

3. Results

Study population and demographics are depicted in table 1. Of the 21 participants recruited, one female subject completed up to the initial lab visit, and one male subject completed up to the second lab visit. Both subjects stated that their schoolwork load was too heavy to complete the intervention. This left $n=19$ who completed the full study. Incomplete data from several subjects left various subject numbers included in each of the final analyses (Figure 1). Data were normally distributed, and no outliers occurred in the set. Subjects decreased their kcal intake between the baseline week and Bite Counter intervention week by -60.3 ± 293.5 kcals, though this result was not significant ($p = 0.383$). When dividing the sample into those who met their daily bite count goal on average and those who did not, 11 met this goal and 7 did not. Equality of variances between the two groups was assessed using Levene's tests. As shown in table 2, the group meeting their goal decreased kcal intake by -142.1 ± 220.2 kcals, while the group who did not increased 115.6 ± 333.3 kcals. This -257.7 kcal difference was not statistically significant, though trended in this direction, (95% CI, -532.69 to 17.24), $t(16) = -1.99$, $p = 0.064$ (figure 1). The intervention demonstrated an effect size of 0.912 regarding kcal intake between week 1 and 2. No significant within-subject differences were observed between baseline and intervention VAS data. When grouped by bite count goal attainment, only a decrease in thirst before bed was significant (95% CI, -1.74 to -0.04), $t(16) = -2.21$, $p < 0.05$.

Figure 1: Varying sample sizes across statistical analyses

Table 1: Demographic characteristics of study participants (n = 19)

Variable	Value
Age (years)	19.53 ± 1.3
BMI (Kg/m ²)	29 ± 3.4
Waist Circumference (cm)	86 ± 16.1
*Body fat % (n=18)	34.8 ± 6.4
⁺ SRER	3.48 ± 0.81
Meals and snacks per day	4.4 ± 1.2
Bites per Minute (n=17)	2.95 ± 0.7
Gender	Female: 16 (84%)
*Race (n=18)	Caucasian: 16 (89%); African-American: 2 (9.5%)

*Varied sample sizes due to missing data: Body fat% and Race: n = 18. Bites per Minute: n = 17

⁺SRER = self-reported eating rate – measured on a 5-point scale: 1: Very Slow – 5: Very Fast

Table 2: Kcal differences based on self-reported bite goal achievement

n = 18	Week 1 Kcal Intake Average (Baseline)	Week 2 Kcal Intake Average (Bite Counter)	Average Kcal Intake Difference (P = 0.064)	P value
SR Goal Achieved (n = 11)	1759.4 ± 533.6	1617.3 ± 434	-142.1 ± 220.2	0.058
SR Goal Not Achieved (n = 7)	1719.6 ± 389.5	1835.1 ± 487.5	115.5 ± 333.2	0.394

Figure 2: Average kilocalorie (kcal) difference between weeks one and two among those meeting their bite count goal, and those who did not, by subject. Self-reported bite count was used to determine goal achievement. A near statistically significant difference in kcal intake was observed between the two groups ($P = 0.064$)

Interestingly, large differences between self-reported bite count, and bite count data extracted from the Bite Counter were observed (figure 2). This analysis was conducted among 16 subjects because of incomplete data. Among these subjects, a mean difference of 28.29 ± 36.97 bites occurred during the intervention week (95% CI, 8.60 to 77.99), $t(15) = 3.06$, $p < 0.008$. When grouped by bite count goal attainment using self-reported bite count, Levene's test revealed that equal variances could not be assumed. Among those meeting their goal, we observed a difference of 11.05 bites. This number increased to 57.03 bites among those not meeting their goal – this difference trended towards significance (95% CI, -95.08 to 3.12), $t(5.5) = -2.35$, $p = 0.061$. Correlation analysis examining self-reported and Bite Counter bite count

data separately showed no significant relationship with kcal intake – no correlation was found between self-reported and Bite Counter bite counts as well.

Figure 3: Self-reported Bite Count vs. Bite Counter Recorded average weekly bite count by subject. A statistically significant difference was observed between these two measures ($P < 0.01$).

Several significant differences among several other parameters were observed when subjects were separated by bite count goal achievement (table 3). Those reaching their average daily bite count goal had higher waist circumference and a lower self-reported bite count. Unexpectedly, those reaching their goal also had a higher kcals-per-bite number than those who did not (figure 3).

Table 3: Between group differences among goal and non-goal achievers

n = 18	Kcals-per-Bite (based on self-reported bite count)	Self-Reported Bite Count	Waist Circumference (cm)
SR Goal Achieved (n = 11)	22.4 ± 7.7	75.8 ± 17.1	92.1 ± 9.7
SR Goal Not Achieved (n = 7)	14.9 ± 3.4	123.8 ± 18.5	76.2 ± 21
P value	<0.05	<0.01	<0.05

Figure 4: Kcals-per-bite using self-reported bite count by individual subject based on bite count goal achievement.

4. Discussion

This study is the first attempt to examine the potential of monitoring daily bite count using the Bite Counter device to decrease kcal intake. Though subjects who met

their bite count goal reduced their kcal intake by 257.6 kcals more than those who did not, these reductions were not statistically significant. No within-group differences were observed between baseline and intervention weeks in VAS appetite profile data, while between group differences show significance in before-bed thirst only.

Based on previous research that found positive correlations between free-living bite count and kcal intake (19, 21), we hypothesized that wearing the Bite Counter would lead to decreases in kcal intake over 1 week, specifically if users met their bite count goal. The lack of statistically significant differences in kcal intake in our intervention is likely due in part to our lack of power, and the large variability we observed within our data set. With no previous research using the Bite Counter in a similar intervention, determining appropriate sample size was difficult, though our intervention did reach a strong effect size of 0.912 with regard to kcal intake difference.

Subjects reaching their bite count goal had a higher mean waist circumference than those who did not. These subjects may have been more motivated to reach their goal than those with smaller waist circumferences (28). Perhaps most surprisingly, those reaching their bite count averaged a higher kcals-per-bite ratio than those not meeting their goal. These findings do coincide with very recent research by Jasper and colleagues, who compared food intake during one meal between a group receiving a low bite count goal (12 bites) and those receiving a higher goal (22 bites) (29). No differences were observed in intake between the two groups, but those in the low bite count goal group took 3.5 g more food per bite on average (29). The researchers speculated that subjects with the low goal took larger bites to prevent any post-meal

hunger that may have been associated with such a low bite count (29). Unlike this most recent research, subjects who met their goal in our intervention decreased their average kcal intake. Thus, over the course of the week-long intervention, our subjects may have compensated less than their subjects during a single test meal. Additionally, their subjects were normal weight and perhaps less motivated to decrease their kcal intake than overweight or obese subjects.

Our study had several limitations. Among them are the short intervention period used. This one-week intervention was chosen to both limit attrition and to gather pilot data for future use. The short length, however, also limits assessment with regard to any behavior changes occurring over time and also in evaluating long-term use of the Bite Counter. With attrition still a major shortcoming in interventions using various technological advances to increase self-monitoring dietary intake (10, 17, 18, 30), future research should assess Bite Counter user preference and behavior changes in the long-term. Along with reliance on self-reported bite count data, large amounts of missing Bite Counter data also limited the validity of the data set. This is exemplified by the statistically significant differences between these two data points. Perhaps contributing to these large differences was the inability of subjects to monitor their data throughout the week using the Bite Counter software, which was only compatible with PCs and not Mac computers. Future studies should assess compliance and user experiences with the Bite Counter, and allow subjects to take advantage of the complete capabilities of the Bite Counter, including using the accompanying software.

Our sample, which included mostly young, educated, females, limits generalizability to other populations as well.

Strengths include using the new technology for the first time in this type of intervention, recruitment of people who wanted to lose weight, controlling for the menstrual cycle, use of validated tools to measure appetite and kcal intake data, and a very low attrition rate. We purposely chose a short study to reduce attrition risk. During this pilot study, we learned that compliance with daily meal Bite Counter should have been recorded - means to enhance this compliance should also be considered in the future.

In continuing efforts to reduce obesity prevalence, technology may play a key role in helping promote behavior change through self-monitoring and goal setting. To our knowledge, this pilot study was the first to test the use of the Bite Counter to decrease kcal intake by decreasing total bite count in free-living settings. It underscores the importance of achieving bite count goal to reduce caloric intake. Future research should focus on longer interventions, with a more varied sample,

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Appendix A: Review of the Literature

Review of the Problem

Self-monitoring and establishing calorie intake goals are effective strategies for achieving weight loss (Burke, Wang, & Sevvick, 2011). Though advances in technology have made this much easier than previously, recording food and beverage intake over long periods of time becomes tedious, and it is rarely maintained (Cordeiro et al., 2015; Laing et al., 2014; Tsai et al., 2007). The Bite Counter is a device worn on the wrist like a watch and records bite counts during an eating session (Dong, Hoover, Scisco, & Muth, 2012). The device can be used to establish a bite count goal to help decrease energy intake without laborious food record keeping (Dong et al., 2012; Scisco, Muth, Dong, & Hoover, 2011). However, the potential for the device to decrease kilocalorie intake has only been tested in laboratory conditions; no studies have examined this in free-living environments (Robinson et al., 2014).

Introduction

Obesity has become a global health issue. It is associated with increased risk for some of the leading causes of preventable death including cardiovascular diseases, stroke, type II diabetes, and some cancers (Ng et al., 2014). In 2013, the American Medical Association House of Delegates defined obesity as a “disease” that requires treatment (*Recognition of Obesity as a Disease, Resolution 420 (A-13)*, 2013). Currently, over 1/3 of U.S. adults are obese (Ogden, Carroll, Kit, & Flegal, 2014). Obese and overweight individuals experience higher inpatient healthcare costs, spend more on prescription drugs, and have more physician visits than their normal-weight

counterparts (Ng et al., 2014). A recent report projected that if current weight gain trends continue, by 2030, 1.35 billion people will be overweight, and 573 million will be obese worldwide (Kelly, Yang, Chen, Reynolds, & He, 2008). For these reasons, implementing successful long-term weight loss interventions is critical to discontinue the current trend.

Overweight/Obesity and Weight Loss

Overweight and obesity are weight status categories determined by calculating an individual's body mass index (BMI), a measurement of weight in kilograms over height in meters squared (Centers for Disease Control and Prevention 2015). Individuals with a BMI between 25.0 and 29.9 are considered overweight, while those with a BMI above 30 are considered obese (Centers for Disease Control and Prevention 2015). Overweight and obesity results from long-term positive energy balance – defined as consistently consuming more kilocalories than expended (McAllister et al., 2009). For this reason, lifestyle modifications aimed at decreasing calorie intake, often while simultaneously increasing energy expenditure, are the primary objectives of treatment in weight-loss interventions (Anton, Foreyt, & Perri, 2011).

The most challenging aspect in treating overweight and obesity through weight-loss interventions is helping individuals who have lost weight maintain the loss in the long-term (Montesi et al., 2016). Weight-loss intervention trials that have implemented various lifestyle modifications with the goal of decreasing kilocalorie intake have shown varying degrees of long-term success, due in large part to how well participants adhere to a program's guidelines (Del Corral, Chandler-Laney, Casazza,

Gower, & Hunter, 2009; DeLany, Kelley, Hames, Jakicic, & Goodpaster, 2014). Still, a large percentage of individuals who do lose weight will gradually regain the lost weight over time (Ng et al., 2014). A 2013 report from the American College of Cardiology, the American Heart Association Task Force on Practice Guidelines, and The Obesity Society states that 35% - 60% of adults participating in an intensive, long-term weight loss intervention maintain a weight loss of $\geq 5\%$ of their initial weight after ≥ 2 years (Jensen et al., 2014). Complicating matters are a multifaceted array of biological, environmental, behavioral, and/or cognitive factors that can contribute to one's ability to maintain a weight loss in the long-term (MacLean et al., 2015).

Although maintaining a long-term weight loss can very difficult, previous noteworthy clinical trials, including Pounds Lost, The Diabetes Prevention Program, and the Look AHEAD trial, have demonstrated that several key components play a strong role in weight-loss and maintenance success (Anton et al., 2012; Group, 2002; Rickman et al., 2011). Among them, include self-monitoring of an individual's data related to weight and activity, which includes factors such as body weight, physical activity and/or daily steps, and food intake (Burke, Wang, et al., 2011; Reyes et al., 2012). Monitoring these data can help individuals identify and change behaviors that may be helping or hindering their goal to lose weight (Gilmore, Duhe, Frost, & Redman, 2014). Self-monitoring is also associated with higher adherence to weight-loss program guidelines (Reyes et al., 2012). In particular, monitoring one's dietary intake and has been demonstrated to be an integral tool for success in helping

individuals lose and manage their weight (Burke, Conroy, et al., 2011; Burke, Wang, et al., 2011; Gilmore et al., 2014; Greaves et al., 2011; Wing & Phelan, 2005).

Continued interaction between the participants and those administering the intervention, such as demonstrated by the Look AHEAD trial, provides therapeutic support to help maintain these behavioral changes, resulting in weight loss over the long term (Wadden et al., 2011).

Although the weight-loss clinical trials mentioned above garnered overall positive results regarding weight loss and weight loss maintenance, they required very intensive lifestyle modifications and dedication from subjects to see results (Gilmore et al., 2014). With frequent, in-person contact to practitioners needed to maintain behavior changes associated with weight loss maintenance, long-term costs for such interventions could add up (Gilmore et al., 2014). Ten-year per capita estimates for medical costs associated with participation in the Diabetes Prevention Program, for example, have been estimated to be around \$4,810 (Herman et al., 2013).

Technology in Self-Monitoring Dietary Intake

Introduction

With highly intensive weight loss interventions costing lots of money, researchers have sought ways to use technology in these programs with the hope of reducing cost and burden to the participant, while maintaining appropriate weight loss maintenance behavior changes (Gilmore et al., 2014). Until recently, self-monitoring of individual dietary intake data used traditional “pen and paper” methods to record food intake and books containing nutrition information for different foods –

information then shared with a practitioner for analysis (Semper, Povey, & Clark-Carter, 2016). Though these methods have demonstrated modest success, monitoring dietary intake using these methods has been found to be very labor-intensive, prone to errors, and can contribute to low user compliance, as well as recall bias in recording food items (Tsai et al., 2007). In recent years, technological advances have replaced traditional pen and paper methods used in self-monitoring data in favor of electronic methods that simplify data collecting and recording and provide immediate feedback to users (Cordeiro et al., 2015). The use of the internet, personal digital assistants (PDAs), and smartphones have provided means to help participants more easily record dietary intake, track physical activity, and communicate more effectively with practitioners anywhere they wish (Gilmore et al., 2014).

Internet/Personal Digital Assistants

One of the first published research studies examining the potential for technology to enhance dietary self-monitoring was conducted by Tate and colleagues in 2001 (Tate, Wing, & Winett, 2001). They found that among 65 overweight adult subjects, the 33 participants using an internet-based behavior therapy program for weight loss – which included submitting weekly electronic self-monitoring dairies – lost more weight and decreased their waist circumference more than those receiving internet educational materials alone (Tate et al., 2001). Researchers also observed a positive correlation between the number of electronic dairies submitted by the internet behavior therapy group and the amount of weight lost (Tate et al., 2001).

Earliest research evaluating the potential for portable technology to ease the burden of dietary intake recording involved the use of PDAs. PDAs accomplish this using features of PDA software programs that can store data, provide users with immediate access to a food and nutrient database of common foods, and provide feedback on choices made (Glanz, Murphy, Moylan, Evensen, & Curb, 2006). In 2006, Glantz and colleagues found that 33 women taking part in the diet modification arm of the Women's Health Initiative significantly increased self-monitoring after beginning to use a PDA to record dietary intake in place of a paper diary (Glanz et al., 2006). Over the course of this one-month trial, participants received immediate feedback on the PDA displaying progress towards their goals, which was then emailed or transmitted to researchers over the internet (Glanz et al., 2006).

Several recent studies further examining the potential of PDAs to facilitate self-monitoring of dietary intake data by comparing a PDA to paper diaries have shown mixed results. Yon and colleagues 2007 found that, although more frequent self-monitoring was associated with higher weight losses, among 176 overweight/obese adults, those using a PDA to self-monitor dietary intake showed no increase self-monitoring frequency over those using a paper diary during a six-month period (Yon, Johnson, Harvey-Berino, Gold, & Howard, 2007). Shay and colleagues 2008 found similar results in weight loss among 39 overweight/obese adults using either a paper diary, a PDA, or web-based diary to record dietary intake over 12 weeks (Shay, Seibert, Watts, Sbrocco, & Pagliara, 2009). Researchers did find, however, that those using their "preferred" method to self-monitor were more likely to comply with recording dietary intake (Shay et al., 2009). Burke and colleagues

2011 also found no difference in weight loss among 192 overweight/obese adults using either a paper diary, or a PDA (Burke, Conroy, et al., 2011). The researchers did find, however, that those using a PDA were more likely to monitor their dietary intake using a PDA over a paper diary (Burke, Conroy, et al., 2011). With regard to dietary adherence, Beasley and colleagues found that in a 4-week weight loss trial with 174 overweight/obese adults, those using a PDA to self-monitor dietary intake adhered more closely to their diet regimen than those using a paper diary (Beasley, Riley, Davis, & Singh, 2008).

Smartphone Applications

Although the research outlined above shows some promise, technological advances to increase dietary intake self-monitoring, much like a paper diary, use of these alternatives still tends to decline over time, though not as quickly (Burke, Conroy, et al., 2011; Tate et al., 2001). Other recent research studies have focused on the potential for smartphone applications or “apps” to ease the burden. Thousands of health care and fitness smartphone apps are available to consumers from the iTunes and Android Marketplace stores, both paid for and free (Gilmore et al., 2014). Research to date examining the efficacy of such smartphone apps for weight loss is limited (Gilmore et al., 2014). Of the studies available, some have focused on a small number of these commercially available applications, while others have tested apps developed by researchers specifically for a study (Gilmore et al., 2014; Semper et al., 2016). App features that make recording dietary intake recording less cumbersome include online access to food nutrient databases, the ability to use a smartphone to

scan product bar codes to easily record kilocalorie and nutrient data, and providing immediate feedback related to calorie intake goals (Gilmore et al., 2014; Semper et al., 2016).

An early example of this technology used to monitor food intake is documented in Tsai et al. (2006), which tested the feasibility of the Patient-Centered Assessment and Counseling Mobile Energy Balance (PmEB) mobile phone application with 15 overweight or obese subjects over a one-month period (Tsai et al., 2007). Researchers found that PmEB application users were more compliant in recording food intake data, more motivated to use the application, found the application more convenient to use, and, though not statistically significant, found it more helpful in calculating caloric balance than using paper methods for record keeping (Tsai et al., 2007). Though the results of this study showed promise, the short duration limits transferability of results to long-time usage (Tsai et al., 2007). A low sample size consisting of mostly white, female, college-educated adults also limits the generalizeability of the results (Tsai et al., 2007).

A more recent study, Carter et al. (2013), piloted a six-month randomized control trial examining the feasibility and acceptability of the My Meal Mate (MMM) smartphone app, which used similar features as those denoted above to record dietary intake data (Carter, Burley, Nykjaer, & Cade, 2013). Among 128 overweight or obese adults, those self-monitoring their dietary intake data using the MMM app adhered more than both those using web-based, or paper methods (Carter et al., 2013). MMM users also rated the app more acceptable and convenient than both the web-based and paper groups (Carter et al., 2013).

Although studies demonstrate that users tend to prefer self-monitoring dietary intake using smartphone apps rather than traditional pen and paper methods, several key shortcomings of these apps have been identified. A 2016 review of six recent studies examining the effects of using smartphone apps to record dietary intake on weight loss over periods between 8 and 24 weeks with healthy overweight/obese adults, found that participants in all six studies lost weight, but not significantly more than those using other methods (Semper et al., 2016). Further, although participants in these studies allocated to the smartphone app group were less likely to drop out than those using other methods for recording dietary intake, app usage still declined over time (Cordeiro et al., 2015; Laing et al., 2014). Laing et al. found that user logins to the MyFitnessPal app over a six month intervention declined rapidly after the first month, from 94 participants initially down to 34 by month six (Laing et al., 2014). Qualitative data suggest that users stop using smartphone apps to log dietary intake for numerous reasons. These include identifying logging into the apps everyday as “tedious” and taking too much time, experiencing difficulties with choosing appropriate food items and amounts, such as when eating food from local restaurants or at parties, and also experiencing difficulties associated with recording in certain locations, such as at a party or buffet (Cordeiro et al., 2015; Laing et al., 2014).

Food Photography

Other researchers have chosen to utilize a smartphone’s camera by using digital images to estimate energy intake. This concept is built upon previous research that examined whether digital photography could be used to more easily measure

energy intake, without the labor associated with weighing plates of food before and after consumption, and the inaccuracies associated with self-report methods, such as 24-hour food recalls, food journals, and food frequency questionnaires (Williamson et al., 2004; Williamson et al., 2003). With this method, users take pictures of their food choices before their meal, and remaining food on their plate once they are finished (Martin et al., 2009). These images are then analyzed by trained dietitians by using photos of standard portions of weighed food for comparison – estimated food amounts are then entered into a computer application to estimate nutrition information (Martin et al., 2009). Several studies have demonstrated the method to be highly reliable and accurate in estimating energy intake in controlled cafeteria settings with both adults (Williamson et al., 2004; Williamson et al., 2003) and children (Martin, Newton, et al., 2007).

Martin and colleagues 2009 used this concept to create a program that could be used in a free-living setting to estimate energy intake by using a smartphone camera to record images (Martin et al., 2009). Using the Remote Food Photography method (RFPM), before and after meals, images taken by users are sent to researchers for analysis using procedures similar to those outlined above (Martin et al., 2009). Analysis, however, has been streamlined and expedited with the creation of a smartphone app called the *Food Photography Application*, which uses a “semi-automated” approach, relying on both human operators and computer imaging algorithms to determine energy intake (Martin et al., 2014). This software also allows users to scan barcodes to identify packaged foods, and can provide them with email or text message reminders to take pictures of their meals (Martin et al., 2014). Three

studies testing the validity and reliability of the RFPM method have demonstrated that it produces reliable energy intake estimates, both when compared to weighed portions of the foods used, and doubly-labeled water, the gold standard for measuring energy intake for humans in free-living environments (Martin et al., 2012; Martin et al., 2009).

Although several other groups of researchers have also used food photography to estimate energy intake (Daugherty et al., 2012; Weiss, Stumbo, & Divakaran, 2010; Zhang, Yu, Siddiquie, Divakaran, & Sawhney, 2015; Zhu et al., 2010), research thus far has focused on testing reliability and validity of this method when compared to others – no research has evaluated this method for use in a weight loss intervention. In addition, like other methods, food photography does have some limitations, including users forgetting to take photos of meals, technical problems with hardware and software, and limitations of computer algorithms (Martin et al., 2014). Based on the research with other methods outlined above, using food photography to self-monitor energy intake may also present problems with attrition, considering the cumbersome nature of taking before and after photos of every food consumed.

Within-Meal Eating Behaviors

Eating Rate

Though technological advances in monitoring dietary intake show some promise, the tediousness of recording dietary intake over long periods remains. Further, none of this technology is capable of monitoring other behaviors related to eating that may be helpful in weight management (Robinson et al., 2014). For

example, within-meal eating behaviors may modify appetite and calorie intake and thus, affect body weight (Robinson et al., 2014). Several observational studies conducted with several different populations have found linear relationships between self-reported eating rate, defined as “grams of solid and liquid food consumed per unit of time” (Petty, Melanson, & Greene, 2013), and obesity. A 1996 study found that, among 438 male fire service personnel age 20-58, those reporting faster eating rates when eating meals at the fire station, gained more weight over a seven-year period than those whose eating rate did not differ by location (Gerace & George, 1996). Several cross-sectional studies in Japan also found statistically significant positive linear associations between eating rate and BMI in various groups, including among 1695 18-year-old healthy women (Sasaki, Katagiri, Tsuji, Shimoda, & Amano, 2003), among 4,742 middle-aged adults (Otsuka et al., 2006), and in among 3,287 adults aged 30-69 (Maruyama et al., 2008). Leong and colleagues 2011 found similar results among 2,500 middle-aged New Zealand women (Leong, Madden, Gray, Waters, & Horwath, 2011). Among recent laboratory studies, researchers have found eating rate to be faster in overweight/obese subjects than normal weight subjects across a wide variety of food (Barkeling, Rossner, & Sjoberg, 1995; Laessle, Lehrke, & Duckers, 2007; Westerterp-Plantenga, Wouters, & ten Hoor, 1991). Van Dongen and colleagues 2011 observed positive correlations between eating rate and both food intake and energy intake (Viskaal-van Dongen, Kok, & de Graaf, 2011).

Experimental studies have also shown promise for the potential of slowing eating rate to reduce food intake. Though results from such studies are mixed, A recent meta-analysis examining twenty-two of these experimental studies, including

those with both normal and overweight/obese adolescent and adult participants, concluded that overall, slower eating rates lead to significant reductions in energy intake (Robinson et al., 2014). Perhaps more importantly, reducing eating rate, along with the ensuing decrease in energy intake, did not produce any significant differences in hunger and satiety compared to those eating at faster rates (Robinson et al., 2014). These results were consistent, regardless of how researchers manipulated eating rate (Robinson et al., 2014).

One such method to manipulate eating rate uses the provision of verbal instructions to subjects, such as instructing them to take smaller bites, put down utensils between bites, and chewing each bite 20-30 times as demonstrated in Andrade et al. 2008, a within-subject study involving 30 young women (Andrade, Greene, & Melanson, 2008). Martin and colleagues 2007 supplied computerized feedback to a group of obese adults in the form of auditory prompts signaling subjects to take bites of food (Martin, Anton, et al., 2007). Ioakimidis et al. 2009 and Zandian et al. 2008 demonstrated the efficacy of a device called a Mandometer, a computer that provides visual feedback on eating rate and records fullness and satiety levels, to subjects among 29 and 47 young adult, normal weight women, respectively (Ioakimidis, Zandian, Bergh, & Sodersten, 2009; Zandian, Ioakimidis, Bergh, Brodin, & Sodersten, 2009).

Currently, no validated method to measure eating rate in free-living environments exists. Though one recent research study provided support for the reliability of self-reported eating rate when compared with meals eaten in controlled, laboratory conditions, the same cannot be said when it was compared to free-living

meals (Petty et al., 2013). A new device, however, may have the potential to accurately record free-living eating rate, and help users decrease it. Researchers tested the validity of the Smart Fork to help users decrease their eating rate (Hermsen et al., 2016). The fork provides light and vibration signals to the user during meals to supply users with real-time feedback on their eating rate (Hermsen et al., 2016). The device can also count and store total bites, meal duration, and percentage of bites eaten too quickly, which can be uploaded to a computer using USB or Bluetooth (Hermsen et al., 2016). Using a software program, users can adjust eating rate parameters in the fork, and view past information recorded on the device (Hermsen et al., 2016). In preliminary testing among a group of 11 young adults using the Smart Fork over a three-day period, the majority of subjects reported eating more slowly and being more aware of how fast they ate (Hermsen et al., 2016). Most users also felt comfortable using the fork and remained motivated to continue using it over the three-day period (Hermsen et al., 2016). Future studies will further evaluate the Smart Fork's potential to help users reduce eating rate and energy intake (Hermsen et al., 2016).

Eating Rate and Physiology

A number of studies in the above-mentioned review on eating rate have proposed several mechanisms through which slowing eating rate decreases food intake without negatively affecting appetite and satiety – results, however, remain mixed (Robinson et al., 2014). Several have examined the effects that slowing eating rate has on a number of gut peptide hormones that play pivotal physiological roles in food intake (Chaudhri, Small, & Bloom, 2006). These include short-acting hormones

released in response to food intake, such as the satiety-inducing hormones peptide YY (PYY), and glucagon-like peptide 1 (GLP1), and ghrelin, an appetite-stimulating hormone that increases during the fasted state (Chaudhri et al., 2006). Rigamonti and colleagues 2013 found that, among normal weight and obese adults and adolescents, obese adolescents who ate slower had higher postprandial levels of GLP1 and PYY (Rigamonti et al., 2013). No significant differences in hormone levels between obese and normal weight adults, however, were observed, with no eating rate effect on hormone levels (Rigamonti et al., 2013). In Kokkinos et al. 2010, among 17 adult normal weight and overweight males, PYY and GLP1 concentrations were significantly higher in those consuming a meal at a slower rate (Kokkinos et al., 2010). No differences in ghrelin response were observed (Kokkinos et al., 2010). Though Galhardo and colleagues 2012 observed similar responses in postprandial PYY between 27 adolescent subjects participating in an intervention aimed at reducing eating rate and standard care control group, within the intervention group, researchers observed lower levels of fasting ghrelin (Galhardo et al., 2012).

In addition to hormonal effects on food intake, slowing eating rate may also help promote satiety through sensory mechanisms. Keeping food in the mouth longer increases oral sensory exposure, which increases opportunity for sensory experiences related to eating, such as taste, texture, and smell (Zijlstra, de Wijk, Mars, Stafleu, & de Graaf, 2009). Several studies have demonstrated that increasing oral sensory exposure time may lead to decreased food intake (Bolhuis, Lakemond, de Wijk, Luning, & Graaf, 2011; Lavin, French, Ruxton, & Read, 2002; Weijzen, Smeets, & de Graaf, 2009). Previous research has also demonstrated that a fast eating rate may

decrease oral sensory exposure time (Forde, van Kuijk, Thaler, de Graaf, & Martin, 2013). Further, slower eating rate may also affect memory differently than eating fast. Ferriday and colleagues 2015 found that adult subjects eating a meal at a slow rate remembered eating a larger portion than fast eaters when asked several hours after consuming it (Ferriday et al., 2015).

Although the above-mentioned studies show promise in reducing eating rate to decrease calorie intake and thus, help people lose weight, most of these studies were conducted in laboratory settings, often with equipment that would be too cumbersome to use in free-living settings. Evidence suggest that even when subjects participate in interventions aimed at decreasing eating rate, it may be difficult to maintain these behaviors in the long-term without significant interaction to help them maintain the behavior change (Spiegel, Wadden, & Foster, 1991).

Bite Counting

A more recent within-meal eating behavior that has become of interest in its potential to decrease calorie intake – perhaps one more easily monitored in a free-living setting – is counting the number of bites of food taken during a meal. A study by West et al 2015 found that, among 41 overweight and obese adults participating in a 5-week study tracking bite count, participants who met a goal of reducing their daily bite count 20%-30% from baseline lost an average of 3.4 lbs, with no changes in physical activity, food selection, portion sizes (West et al., 2015).

A research team from Clemson University in South Carolina have taken this concept and developed a device used to count within meal bites for use as a proxy for

laborious dietary intake recording. Building on the success and popularity of wearable devices that can collect and transmit physical activity data like Fitbits (Gilmore et al., 2014), the Bite Counter is a device worn on the dominant wrist like a watch that uses a build-in gyroscope that measures automated wrist motion to determine bite count (Dong et al., 2012). The Clemson group based this on the idea that in order to place food in the mouth, one must roll their wrist, regardless of food type, utensil or hand use, or position of wrist and body (Dong et al., 2012). The device can be worn all day, and be turned on and off during meals (Dong et al., 2012). The Bite Counter counts and stores bites from each session, and time stamps them, creating a log that can be used to set goals to decrease calorie intake by decreasing bite count (Dong et al., 2012). Accompanying software allows users to view bite count logs and toggle various device display options, including most recent bite count, total daily bite count, as well as most recent calorie and daily calorie counts (Desendorf, Bassett, Raynor, & Coe, 2014). Users can also turn on an alarm on the Bite Counter to alert them when a certain bite count number is reached (Desendorf et al., 2014).

Initial testing of Bite Counter's accuracy was conducted with adults consuming numerous types of foods (Dong et al., 2012). Researchers found the device to be 95% accurate in controlled meal settings, and 86% accurate in uncontrolled eating sessions for detecting bites (Dong et al., 2012). While not perfectly accurate, the device shows promise when one considers the best laboratory tools used to measure intake achieve 95% accuracy and those used in free-living settings achieve 60-80% (Dong et al., 2012). Researchers have also found that 74% of participants preferred using the Bite Counter over dietary intake recording methods, and that the device could save people

an average of 25 minutes daily in estimating and recording calories (Scisco, Muth, & Hoover, 2014).

Very few studies thus far have examined the potential utility of the Bite Counter in reducing energy intake. In Scisco et al. 2011, researchers examined the Bite Counter as a potential tool to reduce eating rate by reducing bite rate or bites-per-minute – a novel approach to decrease energy intake untested before this study (Scisco et al., 2011). Thirty university students, both normal weight and overweight/obese, consumed three identical meals on three separate occasions while wearing the Bite Counter (Scisco et al., 2011). Each meal contained waffles cut up into equal-size pieces (Scisco et al., 2011). In meal #1, subjects ate ad libitum – this provided researchers with a baseline bites-per-minute count and baseline hunger/satiety levels (Scisco et al., 2011). Subjects also ate meal #2 ad libitum, though participants were provided with feedback about their eating rate, which was supplied by the Bite Counter and displayed on a computer screen (Scisco et al., 2011). The final meal mirrored meal #2, though participants were told to maintain an average bite rate throughout the meal equal to 50% of their baseline rate (Scisco et al., 2011). Bite rate data recorded by the Bite Counter were again displayed on the computer screen, with a black line moving across the screen to establish a target for them (Scisco et al., 2011). Researchers found that subjects consumed 70 fewer calories during this final meal than either of the previous two meals (Scisco et al., 2011). These reductions were compounded for those subjects who ate more than 400 calories during their baseline meal, (n=11) eating 164 fewer calories during this final meal (Scisco et al., 2011).

Studies testing utility of the Bite Counter in free-living settings, though few, show promise in the potential of bite count as a proxy for energy intake. In Sisco et al. 2014, researchers found a moderate positive correlation between bite count and calorie intake estimated from automated self-administered 24 hour food recalls when analyzing 2,975 eating activities among 77 men and women, both normal weight and overweight/obese (Sisco et al., 2014). These data mirror preliminary laboratory data examining this association, in which Dong et al. 2010 also found a moderate positive correlation between bite count and calorie intake among 47 young adult male and females over 49 meals (Dong et al., 2012). Though researchers in Sisco et al. 2014 found the kilocalories-per-bite (KPB) differed between males and females – 6 KPB more for males than females – interestingly, no differences in KPB between normal weight and overweight/obese individuals was observed, which seems to contradict previous literature on eating rate among this group (Laessle et al., 2007).

The most recent research using the Bite Counter sought to determine the potential for a bite-based method to estimate kilocalorie intake. The kilocalories per bite equation was developed based on several demographic and physical characteristics, which include sex, age, height, weight, and waist-to-hip ratio (Salley, Hoover, Wilson, & Muth, 2016). The method was developed to be used as a less tedious alternative to estimate energy intake, or when kilocalorie information for foods was unavailable (Salley et al., 2016). Salley and colleagues tested this method with 263 adults and 1,844 food item, and found that the bite-based method was more accurate at estimating kilocalorie intake than when subjects were provided with kilocalorie information for the food items (Salley et al., 2016). This study shows

promise for the Bite Counter to be a valuable tool to help users self-monitor energy intake (Salley et al., 2016).

Conclusion

Busy lives can often hinder weight management efforts. With attrition so high in maintaining behavior changes associated with weight loss, researchers and practitioners are left with the task of finding ways to ease the workload that comes with losing weight and keeping it off. With annual sales of wearable devices projected to increase to over \$50 billion by 2018 (Gandhi & Wang, 2014), harnessing the potential of this technology to help individuals with weight management may play an important role in motivating future research. By addressing dietary intake self-monitoring attrition, and within-meal eating behavior, the Bite Counter may potentially play a helpful role in future weight loss interventions by decreasing the associated workload.

How Many Bites Per Day Do You Take?

Interested in wearing a device that will

You may be eligible to take part in a research study at the University of Rhode Island

Researchers in the department of Nutrition and Food Sciences at URI are conducting a research study to test the use of a wrist-worn device designed to help people in weight loss programs.

If you:

- Are between the ages of 18-48
- Are a non-smoker
- Are not pregnant
- Eat regular meals
- Are interested in losing weight

Contact:

bitecounterstudy@gmail.com
(401) 874-2067

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Department of Nutrition and Food Science
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Title of Project: Wearable Device for Caloric Reduction

CONSENT FORM FOR RESEARCH

You have been invited to take part in a research project described below. The researcher will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, Kathleen Melanson, the person primarily responsible for this study {Phone: (401) 874-4477}, will discuss them with you. You must be between the ages of 18 and 48 years old to participate in this study.

Exclusionary criteria

- Smokers
- BMI <25 or >39
- Age <18 or >48
- Documented eating disorder
- Chronic metabolic disease, such as diabetes or kidney disease
- Use of prescription or over-the-counter medications that affect appetite or energy expenditure
- Pregnant or lactating women

Description of the project:

This study will involve research using the Bite Counter, a device that counts the number of bites of food taken during a meal. The purpose of this research study is to determine the effects of wearing the Bite Counter on calorie intake, appetite, hunger, and fullness. The amount of time required for participation is 3 lab visits over approximately 2 weeks.

What will be done:

If you decide to take part in this study, here is what will happen over the course of the three visits of one and a half hours or less, totaling a lab time commitment of about 4.5 hours: You will first complete a participant screening over the phone to determine if you meet the inclusion criteria. During the first visit to the lab, your height and weight measurements will be taken to confirm the measurements you provided us in the phone screening are accurate. These measurements will be used to determine if you meet the body mass index (BMI) criteria for the study. Visit two will be scheduled 1 week after visit one. Visit three will take place one week after visit 2. In both of these

visits, you will be consuming a test meal to provide us with eating rate measurements and food intake data.

- First visit:
 - As mentioned above, measurements of your height and weight will be taken to determine if you meet BMI criteria. If so, waist circumference, and body composition measurements will be taken. Body composition will be calculated using a Bod Pod, which is a small chamber you will sit in for 1-2 minutes to obtain this data. Wearing tight-fitting clothing will provide you and us with the most accurate measurements.
 - You will complete a questionnaire providing us with some demographic data, including race/ethnicity.
 - You will be given a portion size estimation booklet to help you complete two, unannounced 24-hour dietary recalls by phone in the next week. During these phone calls, we will ask you all the foods and beverages you consumed over the previous 24 hours.
 - You will be given a daily appetite-rating booklet, in which you will rate your appetite each day when you wake up and before you go to bed at night.
 - You will be given instructions for your second visit.
 - You will schedule an appointment for one week after this first visit.
- Second visit:
 - Upon arrival to the lab, you will be asked to empty your bladder. Compliance to test meal instructions provided in visit one will then be assessed
 - You will rate your hunger, satiety, desire to eat, and thirst on a visual analogue scale (a line from 0-10) similar to the ones provided to you in visit one.
 - You will be served generous portions of a lunch meal that you will eat as much of as you like, until comfortably full. While eating this meal, you will wear the Bite Counter, a device worn on the wrist like a watch, to count the number of bites of food you take during this meal. We will provide you with basic instructions on how the device works and tips how to provide us with an accurate bite count.
 - You will again rate your hunger, satiety, desire to eat, and thirst on visual analogue scales upon meal completion, 20 minute following meal completion, and 60 minutes after the start of the meal.
 - You will complete a third 24-hour dietary recall conducted in person.
 - You will be given a Bite Counter to wear for approximately one week and provided brief instructions on how to use it properly, and how it can be used to decrease your calorie intake.
 - You will be given another daily appetite rating booklet (same one from visit one), in which you will rate your appetite each day over the week, when you wake up, and at bedtime.
 - You will be provided with another copy of test meal day instructions.
 - You will schedule an appointment to come in one week after this second visit to complete another test meal.
 - You will complete two more unannounced 24 dietary recalls before your third visit, one week after this visit

- Third visit:
 - This visit will be very similar to visit two. You will consume a second test meal while wearing the Bite Counter and complete another set of visual analogue scales. You will also complete one final 24-hour dietary recall in person.
 - You will return the Bite Counter and receive your monetary compensation.

Risks or discomfort:

There are minimal risks for the following procedures: questionnaires, consumption of a test meal, measures of height, weight, waist circumference, food intake, and appetite. Some minor discomfort may occur with those who are afraid of confined spaces when sitting in the Bod Pod for body composition testing. If you feel uncomfortable, the test will cease and you can exit the Bod Pod.

Benefits of this study:

In an effort to thank them for their time and effort, participants in this study will be awarded a pro-rated stipend upon completion of each lab visit as follows: first visit: \$20.00; second visit: \$20.00; and third visit: \$60.00. The potential benefits to participants in this research study also include obtaining data that may be insightful to their eating habits and potential mechanisms to lose weight. Participants will also receive their own physical and dietary measurements, including body composition results. The potential benefits to society include the possibility of further validation of a wearable device that will potentially help individuals control their eating rate and calorie intake, thereby leading to a helpful, sustainable, low-effort way to achieve healthy weight loss. The research has the potential to provide a valuable piece to weight loss programs, and may help address the need for long-term, sustainable results.

Confidentiality:

Your part in this study is confidential. The information you provide to us will be identified using a code, not your name. This information, which includes a paper copy of each informed consent form, will be stored in a locked file cabinet in the Energy Balance Lab in Ranger Hall, Room 310, to which only the researchers and research assistants will have a key. In addition, the Energy Balance Lab is locked when lab researchers and assistants are not present and only researchers and assistants possess a key to the lab. The electronic version of any private information will be stored on the computer in the lab to which only lab researchers and assistants have the login and password information.

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

In case there is any injury to the subject: (If applicable)

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

Decision to quit at any time:

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

Rights and Complaints:

If you are not satisfied with the way this study is performed, you may discuss your complaints with Dr. Kathleen Melanson, anonymously, if you choose. In addition, if you have questions about your rights as a research participant, you may contact the office of the Vice President for Research and Economic Development, 70 Lower College Road, Suite 2, University of Rhode Island, Kingston, Rhode Island, telephone: (401) 874-4328.

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

Signature of Participant

Signature of Researcher

Typed/printed Name

Typed/printed name

Date

Date

Please sign both consent forms and keep one for yourself.

Wearable Devices Study Lab Screening Interview

ID Number: _____ Date: _____

Interviewer name: _____

1. General Medical History

Do you currently have any medical problems? Yes No

(If yes, check Yes on condition below or specify): _____

Cardiovascular diseases Yes No

Hypoglycemia or low blood sugar Yes No

Kidney or bladder problems Yes No

Stomach ulcers or irritable bowel syndrome Yes No

Diabetes (type 1 or 2) Yes No

Thyroid diseases Yes No

Cancer or adrenal disease Yes No

Alcohol dependency Yes No

Eating disorders Yes No

Do you take any prescribed or over-the-counter medication? Yes No

(If yes, specify) _____

(Any medications affecting appetite such as appetite suppressants?) Yes No

Do you have any food allergies, intolerances or specific foods you avoid? Yes No

(If yes, specify): _____

(Allergies to test meal ingredients including pasta, Romano cheese, olive oil, celery, garlic, tomato paste or diced tomatoes?) Yes No

Are you following a special diet? Yes No

(If yes, specify) _____

Are you pregnant? Yes No

(If no, "What was the date of the first day of your last period?") _____

Do you smoke cigarettes? Yes No

Are you able to abstain from caffeine more than 1 day? Yes No

Meets Health Criteria.

Yes No

2. Anthropometrics

MEASURE HEIGHT AND WEIGHT FOLLOWING PROTOCOL

Height: _____ (cm)

Weight: _____ (lbs)

BMI kg/m² _____

Waist circumference: _____ (cm)

Meets BMI Criteria:

Yes No

BOD POD TESTING: Body Composition Results: *Lean Mass* _____ *Fat*
Mass _____

3. Eating Patterns/Eating Rate

Do you eat in “defined” meal times? _____

How many meals and snacks do you usually eat per day? _____

Meets Eating Pattern Criteria

Yes No

What is your usual rate of eating? (Circle one):

Very Slow Slow Medium Fast Very Fast

What is your personal desired body weight? _____

4. Demographics

Birth date: _____ Age: _____ Gender _____

Race/Ethnicity you identify with (check those that apply; please note that **this section is optional** and will not affect subject's eligibility to participate in study):

Ethnicity: ☐ Hispanic or Latino
☐ Not Hispanic or Latino
Race: ☐ American Indian or Alaskan Native
☐ Asian
☐ Black or African American
☐ White
☐ Other: _____

5. FEMALE SUBJECTS:

What is the date of the beginning of your last menstrual period? _____

How long does your overall menstrual cycle usually last? _____

First lab appointment can be made on days 6 – 11 days of menstrual cycle (for cycles lasting ≥ 28 days). This will ensure that the subject will be able to complete the two-week study before the late luteal phase and menses.

V1 date and time: _____

V2 date and time: _____

V3 date and time: _____

Females:

Cycle Days of: V1 = _____

V2 = _____

V3 = _____

CHECK:

Education provided for Test Meal? _____

Education provided for 24 hour recalls? _____

Does subject have booklet for phone recalls: _____

Does subject have a FLAP? _____

Participant Initials: _____

Contact number: _____

Week 1 Record

Subject Initials			Number (leave blank)				Today's Date		

UPON AWAKENING (BEFORE BREAKFAST)

Clock time: _____ ☐ am ☐ pm

1. How hungry are you right now?

Not at all

Extremely

2. How satisfied are you right now?

Not at all

Extremely

3. How much could you eat right now?

Nothing

Vast Quantities

4. How thirsty are you right now?

Not at all

Extremely

BEFORE BED

Clock time: _____ ☐ am ☐ pm

1. How hungry are you right now?

Not at all

Extremely

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

Not at all

Extremely

3. How thirsty are you right now?

Not at all

Extremely

4. How does the amount you ate today compare to your normal day?

Much less

Much more

5. Overall, how hungry have you been today compared to your normal day?

Much less

Much more

Thank you for completing today's Appetite Profile!

Bite Count Record and Goal Setting Sheet

Please wear the bite counter for the rest of the day and record the number of bites under Day 0 just to get used to the process. The next day (Day 1), record the number of bites and look at the chart on page 2 to help set a goal for Day 2. Your goal should be about 10% below your usual intake which you are estimating from Day 1. Write the goal for Day 2 on the chart. On Day 2, record your bites and compare to your goal. If your goal was too hard, chose a higher bite count goal for Day 3. If your goal was too easy, choose a lower bite count goal for Day 3. Repeat as needed until you have a goal that works for you. Try to follow the goal the rest of the week. To get an idea of approximately how many calories you may be taking per bite – so as not to consume too few calories – if you are <5'4" then 1 bite = approximately 21 calories; if you are > 5'4" but less than 5'10" then 1 bite = approximately 25 calories; if you are > 5'10" then 1 bite = approximately 30 calories.

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

Total Daily Bite Count (Day 1)	Bite Count Goal for Remainder of Week
≤75	65
76-80	70
81-85	75
86-90	79
91-95	84
96-100	88
101-105	93
106-110	97
111-115	102
116-120	106
121-125	111
126-130	115
131-135	120
136-140	124
141-145	139
146-150	133
155-160	138
156-160	142
161-165	147
166-170	151
171-175	156
176-180	160
181-185	165
186-190	169
191-195	174
196-200	178

Appendix C: Additional Statistical Output

Paired Samples Test: Vas Scale Differences Between Week 1 and Week 2

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	IVAS_MH - CVAS_MH	-.1467	1.1668	.2750	-.7269	.4335	-.533	17	.601
Pair 2	IVAS_MS - CVAS_MS	.1672	.9660	.2277	-.3132	.6476	.734	17	.473
Pair 3	IVAS_MDTE - CVAS_MDTE	.0994	1.2883	.3036	-.5412	.7401	.327	17	.747
Pair 4	IVAS_MT - CVAS_MT	-.2544	.9064	.2136	-.7052	.1963	-1.191	17	.250
Pair 5	IVAS_BBH - CVAS_BBH	-.0711	.9453	.2228	-.5412	.3990	-.319	17	.754
Pair 6	IVAS_BBS - CVAS_BBS	.2850	1.1384	.2683	-.2811	.8511	1.062	17	.303
Pair 7	IVAS_BBT - CVAS_BBT	-.2794	.9235	.2177	-.7387	.1798	-1.284	17	.216
Pair 8	IVAS_Amount - CVAS_Amount	.0600	.7723	.1820	-.3241	.4441	.330	17	.746
Pair 9	IVAS_Overall - CVAS_Overall	-.2344	1.1567	.2726	-.8096	.3408	-.860	17	.402

**VAS Scale Differences Between Week 1 and Week 2 When Grouped By Bite
Count Goal Achievement**

		t	df	Sig. (2-tailed)	95% Confidence Interval of the Difference	
					Lower	Upper
VAS_MH_Difference	Equal variances assumed	1.184	16	.254	-.52202	1.84202
	Equal variances not assumed	1.461	11.760	.170	-.32652	1.64652
VAS_MS_Difference	Equal variances assumed	-1.364	16	.191	-1.58768	.34430
	Equal variances not assumed	-1.332	11.907	.208	-1.63982	.39644
VAS_MDTE_Difference	Equal variances assumed	1.833	16	.086	-.16763	2.30711
	Equal variances not assumed	2.121	15.282	.051	-.00375	2.14323
VAS_MT_Difference	Equal variances assumed	-1.277	16	.220	-1.46183	.36261
	Equal variances not assumed	-1.298	13.617	.216	-1.45992	.36070
VAS_BBH_Difference	Equal variances assumed	-.133	16	.896	-1.06080	.93560
	Equal variances not assumed	-.142	15.467	.889	-.99794	.87275
VAS_BBS_Difference	Equal variances assumed	-.666	16	.515	-1.55922	.81350
	Equal variances not assumed	-.602	9.103	.562	-1.77200	1.02629
VAS_BBT_Difference	Equal variances assumed	-2.208	16	.042	-1.74395	-.03553
	Equal variances not assumed	-2.020	9.501	.072	-1.87827	.09879

VAS_Amount_Difference	Equal variances assumed	.085	16	.933	-.78305	.84851
	Equal variances not assumed	.089	14.715	.930	-.75335	.81880
VAS_Overall_Difference	Equal variances assumed	.170	16	.867	-1.12301	1.31885
	Equal variances not assumed	.179	14.969	.860	-1.06834	1.26419

Correlation Analysis Between Self-Reported and Bite Counter Bite Counts and Intervention week Kilocalorie Intake

		BC_Cal	Avg_wk_SR_B C	Avg_wk_BC_B C
BC_Cal	Pearson Correlation	1	-.040	-.065
	Sig. (2-tailed)		.879	.804
	N	18	17	17
Avg_wk_SR_BC	Pearson Correlation	-.040	1	-.052
	Sig. (2-tailed)	.879		.847
	N	17	18	16
Avg_wk_BC_BC	Pearson Correlation	-.065	-.052	1
	Sig. (2-tailed)	.804	.847	
	N	17	16	17

**Repeated Measures ANOVA: Time * Self-Reported Bite Count Goal
Achievment**

Tests of Within-Subjects Contrasts

Measure: Kcals

Source	time	Type III Sum of Squares	Df	Mean Square	F	Sig.
time	Linear	1509.966	1	1509.966	.042	.840
time *	Linear	142037.225	1	142037.225	3.948	.064
Met_BC_Goal_Avg_SR						
Error(time)	Linear	575651.156	16	35978.197		

Tests of Between-Subjects Effects

Measure: Kcals

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	102760253.858	1	102760253.858	253.293	.000
Met_BC_Goal_Avg_SR	67807.523	1	67807.523	.167	.688
Error	6491144.718	16	405696.545		

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