

Do Weight Status and the Level of Dietary Restraint Moderate the Relationship between Package Unit Size and Food Intake?

A Thesis Presented for
the Master of Science
Degree
The University of Tennessee-Knoxville

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May 2013

ACKNOWLEDGEMENTS

To my major professor, Dr. Hollie Raynor, a heartfelt thank you for being such a wonderful advisor and mentor to me over the years. Thank you for your time and dedication to helping me grow as both a student and a professional.

To my committee members, Drs. Melissa Hansen-Petrik and Michael Zemel, thank you for your constructive feedback and guidance throughout this process.

To the undergraduate and graduate students in the Healthy Eating and Activity Laboratory, thank you for your assistance and continual support.

To my family and friends, thank you for being the cheerleaders I need in my life.
A very special thank you to my parents, Jeffery and Wenonah Haire, for always believing in me.
Without your encouragement, love, and advice, I would not be where I am today.

ABSTRACT

Background: Package unit size may influence consumption. Single-serving (SS) packages, as compared to larger, standard (ST) packages, may increase awareness of what a standard serving is and assist in reducing consumption. Individuals who may be concerned about the amount they consume, such as overweight (OW) and dietary restrained individuals, may be more influenced by SS packages. Thus, the purpose of this study was to examine if weight and dietary restraint status moderate the influence of package size on consumption. It was hypothesized that SS packages would help to reduce intake in OW and/or restrained individuals as compared to normal weight (NW) and/or unrestrained individuals.

Methods: Using a 2x2x2 (unrestrained/restrained x NW/OW x SS package/ST package) between-subjects factorial design, the effects of weight and restraint status on the relationship between package unit size and food intake were examined in 64 participants in a natural environment. NW and OW, unrestrained and restrained participants (23.7 ± 3.3 years; 81.3% white; 96.9% non-Hispanic) were randomly assigned to receive either 20 ounces of pretzels packaged in SS packages or ST packages to eat ad libitum for 4 days. Total grams of pretzels consumed was determined by subtracting pre- and post-consumption weight of packages provided.

Results: Using a 2x2x2 analysis of variance, for total grams of pretzels consumed, there was a significant interaction between package unit size and weight status ($F(1,56)=7.1, p=0.01$). Pairwise comparisons showed that OW participants in the ST size condition ate ($p<0.05$) more grams of pretzels (204.4 ± 144.9 g) compared to OW participants in the SS condition (107.0 ± 101.9 g). Pairwise comparisons also revealed that for participants in the ST size condition, OW participants ate ($p<0.05$) more grams of pretzels (204.4 ± 144.9 g) than NW

participants (112.7 ± 58.9 g). No significant difference was found between OW and NW participants in the SS condition for grams of pretzels consumed (107.0 ± 101.9 g vs. 158.1 ± 104.4 g, respectively).

Conclusion: Results from this study suggest that for OW individuals, ST packages increased consumption as compared to SS packages, which did not occur for NW individuals. While SS packages may not influence OW individuals to eat less in comparison to NW individuals, replacing ST packages with SS packages may assist with reducing overconsumption.

TABLE OF CONTENTS

CHAPTER I: LITERATURE REVIEW	1
Background and Significance	2
- Introduction	2
- Studies Investigating Increasing Portion Size/Unit Size Across Time	4
- Studies Investigating the Combined Effects of Portion Size/Unit Size on Food Intake	6
- Studies Investigating the Independent Effects of Portion Size and Package Unit Size on Food Intake	13
- Studies Investigating Package Unit Size and Food Intake	15
Conclusion	19
- Summary	19
- Specific Aims	21
CHAPTER II: MANUSCRIPT	23
Introduction	24
Experimental Design & Methodology	27
- Study Design	27
- Participants	27
- Procedure	30
- Compensation	31
- Pretzel Package Unit Size	32
- Measures	32

- Statistical Analyses	34
Results	35
- Participant Characteristics	35
- Location of Pretzel Consumption	37
- Measured Pretzel Consumption	37
Discussion	38
References	45
APPENDICES	49
- Appendix A: Tables and Figures	50
- Appendix B: Flyers, Forms, and Questionnaires	57
VITA	89

LIST OF TABLES

Table 1. Depiction of study design – complete 2x2x2 between-subjects factorial design.	51
Table 2. Baseline characteristics of participants ($M \pm SD$).	52

LIST OF FIGURES

Figure 1. Percent of pretzel consumption occurring outside the home over a 4-day period in all eight groups.	54
Figure 2. Total grams of pretzels consumed over a 4-day period in all eight groups.	55
Figure 3. Total grams of pretzels consumed over a 4-day period in normal weight and overweight participants.	56

CHAPTER I
LITERATURE REVIEW

BACKGROUND & SIGNIFICANCE

Introduction

According to data from the 2007-2008 National Health and Nutrition Examination Survey, the estimated prevalence of obesity among adults was 33.8% and the combined estimated prevalence of overweight and obesity was 68.0% (1). These rates have increased over the years and continue to rise (1). Over the past three decades, obesity has become a public health priority due to its strong association with reduced quality of life and its link to increased risk for chronic diseases, such as coronary heart disease and diabetes (2, 3). Obesity is a consequence of positive energy balance from either an increase in energy intake and/or a decrease in energy output (2).

Although there are no clear reasons for the current obesity epidemic, there is a general consensus that environmental dietary factors, such as portion size and package unit size, encourage excessive food intake and positive energy balance (4, 5). Studies investigating the influence of these environmental dietary factors on food intake use terminology that has changed in definition over the years (6-10). For example, some studies refer to portion size as the amount of food provided to an individual per eating occasion, others refer to portion size as the unit size of a food/food package, and still others refer to portion size as both the amount of food and the unit size of a food/food package (9). In this literature review, so that previous research may be interpreted consistently, portion size will be defined as the amount of food provided to an individual per eating occasion, while package unit size will refer to the amount of food provided within a specific unit or package size. The definitions of these two factors can best be explained through examples. The portion size of food refers to the quantity of food presented to an individual. So, if a person was presented with one, 5-ounce bag of pretzels or five, 1-ounce bags

of pretzels, the amount of food that has been presented is 5 ounces, and that would be considered the portion size. However, since package unit size of food refers to the size of a single serving unit of food presented to an individual, in the previous example, two package unit sizes were presented: 5-ounces and 1-ounce. This paper will present findings categorized by the above definitions, even though the authors may use different terminology.

It is important to distinctly define the constructs of amount of food and food unit/package size as it has been proposed that these factors, which are components of the food environment, indirectly influence food intake through two distinct mechanisms (5). Specifically, the amount of food available is believed to affect consumption volume by suggesting consumption norms, while the size of food packaging may affect consumption volume by impacting the accuracy of consumption monitoring (4, 5, 9). The amount of food in the environment may serve as a consumption norm by suggesting what is a suitable volume of food to consume per eating occasion (5, 9-11). It can also serve as a cue, such that in providing an individual with more food, the individual eats more simply because more food is made available for consumption (9). Food package unit size may impact the accuracy of consumption monitoring and thus, impact food consumption (5, 9). Large packages containing multiple servings of food can decrease the accuracy of consumption monitoring by making it difficult for an individual to assess how many servings have been consumed in one sitting (9). On the contrary, small packages containing a single serving can increase the accuracy of consumption monitoring by providing a clear definition of what a standard serving is and how much one has consumed (9, 10).

While portion size appears to influence food intake independent of individual characteristics (9, 12, 13), food package unit size may not influence consumption equally in all individuals (9, 14, 15). If food package unit size impacts on intake through influencing accuracy

of consumption monitoring, individual characteristics that may moderate the degree of occurrence of consumption monitoring, such as weight status and dietary restraint, may also moderate the relationship between food package unit size and intake (14, 15). For example, overweight and/or dietary restrained individuals may engage in consumption monitoring more so than non-overweight and/or dietary unrestrained individuals in efforts to control energy intake. Dietary restraint is a term that refers to the amount of control exerted over food intake, irrespective of physiological cues, such as hunger and satiety (16, 17). Thus, unrestrained eaters do not monitor and limit the amount of food they consume, while restrained eaters closely monitor and tightly control the amount of food they consume, regardless of hunger and satiety levels. Dietary restraint is commonly measured by the Three Factor Eating Questionnaire (TFEQ), developed by Stunkard and Messick (16, 17). This validated and reliable tool measures three dimensions of eating behavior: dietary restraint, disinhibition, and hunger (17). Dietary restraint is scored with values ranging from 0-21, with 0 being a completely unrestrained eater and 21 being a completely restrained eater (17). Thus, in summary, overweight individuals or restrained eaters who are trying to control or limit food intake may more closely monitor the volume of food they consume (9). It follows then that [smaller] sizes of food packaging (particularly in the unit size of a more standard serving size) may aid in monitoring of food consumption and therefore, allow individuals to control/limit overall energy intake.

Studies Investigating Increasing Portion Size/Unit Size Across Time

Over the past several decades, it appears that food portion size/unit size has increased (18-20). A few recent studies concluded that portion sizes/unit sizes of food that individuals serve themselves, as well as the portion sizes/unit sizes of food being served to individuals, have increased over the past several decades and that this has coincided with the rise in prevalence of

overweight and obesity among Americans (18-20). Although these studies state that portion sizes were investigated, they failed to tease apart the variables, portion size and unit size. For example, two of the studies found that the portion size of pasta had increased over the time periods examined, but if using the definitions provided in the introduction, both the portion size and unit size increased (19, 20). The amount of food presented to the individual increased (portion size), as well as the size of a single serving unit of the food (unit size).

A study conducted by Smiciklas-Wright and colleagues (19) examined the quantities/sizes of foods consumed in 1989-1991 and 1994-1996 as reported in the Continuing Survey of Food Intakes by Individuals (CSFII), a survey conducted by the United States Department of Agriculture (USDA). This study looked at the portion sizes/unit sizes for 107 different foods/food types that individuals served themselves in the home environment in both 1989-1991 and 1994-1996 and found that nearly one-third of the foods/food types significantly differed in portion sizes/unit sizes, with the majority showing an increase. To add to the findings of this study, Nielsen and Popkin (18) used data from three nationally representative surveys to discover trends in food portion sizes/unit sizes in the United States by eating location and food source between 1977-1998. As with the previous study, it was found that portion sizes/unit sizes for specific foods, such as salty snacks, soft drinks, and hamburgers, have increased significantly over time. The increases in portion sizes/unit sizes occurred both inside and outside the home, meaning that both the portion sizes/unit sizes of foods individuals serve themselves and the portion sizes/unit sizes of food being served to individuals have increased. The greatest increases in portion sizes/unit sizes were found at fast food establishments, followed by the home and other restaurants. Adding to this, Young and Nestle (20) found that fast food establishments now offer portions/units two to five times larger than the standard size, which corroborates the

finding that portion sizes/unit sizes of food being served to individuals have increased since the 1970s. These studies provide evidence in support of increasing portion sizes/unit sizes in the United States during the same time period in which the prevalence of obesity has increased (3, 18-21). However, for portion size/unit size to be considered a causative factor in obesity, portion size/unit size must be related to energy intake.

Studies Investigating the Combined Effects of Portion Size/Unit Size on Food Intake

There has been much research in recent years describing how portion sizes/unit sizes affect energy intake (6-8, 12, 13, 22-26). Studies in this area of research have been conducted in both laboratory and natural settings, which provide both internal and external validity to the findings (6-8, 12, 13, 22-26). As with the studies investigating the changes in portion sizes/unit sizes over time, the studies in this section also treated the two variables, portion size and unit size, as one. Therefore, it is unclear whether the effect found was due solely to the amount of food presented to an individual or if the effect was related to both the amount of food and the unit size of food presented to an individual. So, even though the researchers in these studies state that they were examining the impact of portion size on food intake, the following studies discussed will be ones that have combined the two variables, portion size and unit size.

Rolls and colleagues (6-8, 12, 13) have conducted a series of well-controlled studies in laboratory settings that add to the body of evidence supporting the hypothesis that increases in portion size/unit size lead to increases in energy intake. In one study, Rolls and colleagues (8) fed fifty-one unrestrained, normal-weight and overweight men and women a lunch of macaroni and cheese one day/week for four weeks, varying the portion sizes/unit sizes of the entrée (500, 625, 750, or 1000 g) each time it was served. Participants were divided into two groups, one of which was to receive the macaroni and cheese on a plate and another of which was to receive the

macaroni and cheese in a serving dish from which they could serve themselves (8). This division among participants was done to determine if the effects of the study differed in situations where participants were given a specific portion/unit of food on their plate as compared to situations where participants were allowed to decide the quantity of food on their plate. In the first condition, because the participants were served the macaroni and cheese on individual plates, both the amount of food and the unit size of food increased simultaneously. In the second condition, only the amount of food was manipulated (increased). There was no clear unit of food presented to the participants because the participants were allowed to serve themselves from a large serving dish. Participants in both groups ate significantly more macaroni and cheese when given the larger portion sizes/unit sizes, regardless of if the food was provided on a plate or in a serving dish from which they served themselves. Combined, participants ate 30% more food and energy from the largest portion/unit of 1000 g in relation to the smallest portion/unit of 500 g. Results of the analysis of weight status and level of dietary restraint indicated that there was no effect of those participant characteristics on the relationship between portion size/unit size and food intake (8). Thus, it seems that the amount of food (portion size) does not interact with individual characteristics to alter food intake. Interestingly, although intakes increased with larger portions/units, the changes in before and after lunch ratings of hunger and satiety did not differ for participants in either group. This implies that when presented with a larger amount/unit of food, participants ate more before reaching a maximum level of fullness, but feelings of fullness were not affected by total gram amount consumed (8).

In another study by Rolls and colleagues (6), they discovered that when individuals were served varying portion sizes/unit sizes of a deli-style sandwich (6, 8, 10, or 12 inches), sandwich intake increased as portion size/unit size increased. Participants were primarily of normal weight

and low dietary restraint status. When participant characteristics were analyzed, no correlation was found between weight status and level of dietary restraint in relation to portion size/unit size and food intake (6). Thus, portion size/unit size of food had no interactive effect with individual characteristics to alter food intake. Ratings of hunger and satiety were not significantly different after consuming the three larger sandwich sizes, even though intake was significantly different (6). These results demonstrate that portion size/unit size within a meal influenced food intake. In a separate study conducted by Rolls and colleagues (7) on sixty normal weight, unrestrained participants, it was found that as the portion size/unit size of packaged potato chips increased (both amount of potato chips and package unit size increased), energy intake increased significantly. An analysis of covariance found no effect of weight status or level of dietary restraint on the relationship between portion size/unit size and food intake (7).

In the previous investigations, the influence of portion size/unit size was only investigated within one eating bout. However, compensation to increased energy intake due to large portion sizes/unit sizes at one meal could occur at a later eating bout. If compensation at later eating bouts does occur, then greater portion sizes/unit sizes in any particular eating bout would not then be problematic for energy balance. Therefore, Rolls and colleagues (12, 13) conducted two studies in controlled settings to determine the effect on overall energy intake when portion sizes/unit sizes were increased over the course of two and eleven consecutive days, respectively. In the 2-day study, normal weight/overweight, unrestrained participants ate breakfast, lunch, and dinner for two consecutive days in the laboratory for three separate weeks (13). In each of the three weeks, participants were served either 100%, 150%, or 200% of the baseline amount of food/beverages. Some menu items increased only in portion size, while others increased in both portion size and unit size. For example, the French toast sticks served

for breakfast remained the same unit size (size of each stick was consistent), but increased in portion size (number of sticks served were increased). The chocolate pudding served for lunch, however, increased in both portion size (larger amount) and unit size (larger unit of pudding in bowl). The baseline caloric amount of food/beverages was greater than 3000 kcal/day for women and greater than 3900 kcal/day for men, an amount that was greater than 135% of estimated energy requirements. These baseline caloric amounts were in excess of estimated energy requirements in order to ensure that the baseline daily menus provided adequate caloric amounts of food/beverages to fulfill participants' energy needs. The baseline portion sizes/unit sizes of food/beverages served to the participants were then increased by 150% or 200% in the weeks designated for those two experimental conditions. All portion sizes/unit sizes of food/beverages served to participants were increased, with the exception of water, coffee, tea, and packaged salad dressing and spread (13). All foods and beverages were provided to participants, thus participants did not serve themselves. When served 150% of the baseline, participants ate 16% more food/beverages (335 kcal/day more for women and 504 kcal/day more for men) and when served double the baseline, participants ate 26% more food/beverages (530 kcal/day more for women and 812 kcal/day more for men). Thus, increasing the portion sizes/unit sizes of food/beverages provided at meals increased energy intake. There was no significant difference in overall energy intake between the two consecutive days by each experimental condition, suggesting that in this short timeframe participants did not compensate for excess energy intake on the first day by decreasing intake on the second day. Also, there was no effect of weight status and level of dietary restraint on the relationship between portion size/unit size and food intake (13). Thus, participant characteristics in conjunction with these dietary environmental variables did not impact food intake.

In a second study, when the portion sizes/unit sizes of all food/beverages were increased by 50% for eleven consecutive days, results were consistent with those in the 2-day study (12). In this study, normal weight and overweight, primarily unrestrained participants were first served baseline portion sizes/unit sizes of food/beverages for a period of eleven consecutive days, and following a 2-week washout period, were then served portion sizes/unit sizes that had been increased by 50% of the baseline portion sizes/unit sizes for another period of eleven consecutive days. As in the 2-day study, the baseline portion sizes/unit sizes of the food/beverages served to participants was determined by providing an amount that was in excess of estimated energy requirements. This ensured that the baseline daily menus provided adequate caloric amounts of food/beverages to fulfill participants' energy needs. The baseline amount of energy served to women was approximately 3400 kcal/day over the 11-day period, while that for men was 4100 kcal/day over the 11-day period. Following a 2-week washout period, the participants were then given the same 11-day menu with the portion sizes/unit sizes increased by 50%. For each 11-day period, the food/beverages were provided to the participants and thus, they did not serve themselves. When the portion sizes/units sizes of food/beverages were increased by 50% for eleven days, participants had an average increase in intake of 423 kcal for each day of the study, resulting in an overall increase of 4636 kcal over the length of the study. The 50% increase in portion sizes/unit sizes also led to significantly greater intakes of food/beverages by weight, with the participants consuming approximately 286 g more each day over the 11-day period than in the baseline condition. Energy intake by each condition did not significantly differ across study days, strengthening the findings of the previous study that the effect of large portion sizes/unit sizes on energy intake is sustained over a period of days. As in the 2-day study, there was no effect of weight status or level of dietary restraint on the relationship between portion size/unit

size and energy intake (12). Thus, these participant characteristics did not seem to interact with portion size/unit size to influence food intake.

Studies conducted in natural settings have also found that large portions lead to greater energy intake (22, 25, 26). In two separate studies conducted in a movie theater, Wansink and colleagues (25, 26) found that moviegoers ate significantly more popcorn from large containers than from medium ones. Both amount of popcorn and container size of popcorn increased, so portion size and package unit size were treated as one variable in these studies. In one study, moviegoers were given either fresh or stale, 14-day-old popcorn and it was found that energy intake increased (45.3% and 33.6%, respectively) when portion size/container size increased, regardless of the taste (25). In the other study, moviegoers were split into two groups based on their ratings of perceived taste of the popcorn (relatively favorable taste versus relatively unfavorable taste) (26). Interestingly, those who rated the popcorn as relatively unfavorable ate 61% more popcorn from large containers, while those who rated the popcorn as relatively favorable only ate 49% more. Both studies support the idea that increased portion sizes/unit sizes lead to increased consumption, even when foods are not palatable. Because these studies were conducted in natural settings, participant characteristics were not described and thus, were not analyzed to see if there was an effect of participant characteristics on the relationship between portion size/unit size and food intake.

In another study conducted in a natural setting, Diliberti and colleagues (22) found that increasing the portion size/unit size of a restaurant meal had a significant effect on energy intake. In fact, when customers purchased a baked pasta entrée 150% larger than the standard size, they consumed 43% more energy than customers who purchased the standard-sized entrée. Overall, when the 150% larger portion size/unit size entrée was purchased, customers increased their

entire meal energy intake by 25% compared with the standard-sized meal (22). This increase for the entire meal (25%) is lower than the increase for the larger entrée alone (43%) because customers consuming the standard-sized entrée had higher energy intakes of optional items, such as desserts and beverages, than did the customers purchasing the 150% portion size/unit size baked pasta entrée. Altogether, though, customers purchasing the larger portion/unit significantly increased their energy intake of the entire meal. As in the Wansink studies (25, 26), because this study was conducted in a natural setting, the researchers were not able to gather accurate data on subject characteristics (22). However, the body size of customers was estimated in this study in order to determine if there was an effect of body size on the relationship between portion size/unit size and food intake (22). Body size of customers (about 67% underweight/normal weight; about 33% overweight/obese) was found to have no effect on the relationship between portion size/unit size and food intake (22). Thus, it appears that weight status did not interact with portion size/unit size to impact food intake.

If increasing portion size/unit size of food increases intake, reducing these factors may result in decreasing intake. To test this theory, Rolls and colleagues (27) recently conducted a study looking at the effects of both reduced portion size/unit size and reduced energy density on energy intake of normal weight, unrestrained women over a 2-day period. Rolls and colleagues found that both reduced portion size/unit size and energy density caused significant and independent reductions in energy intake. When researchers specifically looked at the amount/unit size of food presented to participants, they discovered that reductions in portion size/unit size by 25% of the baseline amount resulted in a 10% decrease in intake by food weight, irrespective of the energy density of the food. The 10% reduction in intake by food weight corresponded to a 10% reduction in energy intake, demonstrating that reductions in

portion size/unit size lead to significant and sustained decreases in food intake by both weight and calories. No significant differences were found in energy intake at each meal over the course of the two days. Thus, participants did not compensate for decreased food intake at one meal by increasing food intake at another. Furthermore, ratings of hunger and satiety did not significantly differ over the course of the two days, providing evidence that these results were obtained without increasing the hunger of participants and possibly leading to overeating at later meals (27). When participant variables, such as weight status and level of dietary restraint, were examined, it was found that they had no effect on the relationship between portion size/unit size and food intake. Thus, it seems that these participant characteristics do not interact with food portion size/unit size to alter one's food intake.

These studies, both in the laboratory and in more natural settings, suggest that increased portion sizes/unit sizes lead to increased energy intakes, and that the increased intake from greater portion sizes/unit sizes is not compensated over time (6-8, 12, 13, 22, 25, 26).

Additionally, when both portion size and unit size are modified simultaneously, individual characteristics, such as weight status and dietary restraint, do not appear to influence the relationship between portion size/unit size and intake.

Studies Investigating the Independent Effects of Portion Size and Package Unit Size on Food Intake

The above studies combined the dietary environmental variables, portion size and package unit size. Thus, as amount of food presented to participants increased/decreased, so did the unit size of the food. Because of this, it was impossible to determine which dietary environmental variable (or both) was having an effect on food intake. Raynor and Wing (9)

were one of the first to demonstrate that these variables can be teased apart and studied individually to discover their independent effects on food intake.

In a study investigating the influence of portion size and package unit size on food intake, Raynor and Wing (9) randomly assigned unrestrained, primarily normal weight college-aged participants to one of four groups crossing portion size (small versus large) and package unit size (small versus large). Participants were given various snack foods corresponding to their respective group (small amount/small package unit of food; small amount/large package unit of food; large amount/small package unit of food; large amount/large package unit of food) to take home and consume over a period of three days. Single-serving packages of four different snack items were given to participants in the small unit condition, while snack packages at least five times the size of the single-serving snack packages were given to participants in the large unit condition (ex: 1 oz. versus 5 oz.) (9). For the small portion size condition, participants were given packages of the same four snack items with an amount of food that provided about 4350 kcal (9). For the large portion size condition, participants were given packages of the four snack items with an amount of food that provided about 8750 kcal (double the amount of the small portion size condition) (9). Upon completion of the study, it was discovered that package unit size (small versus large units) had no significant effect on the participants' energy intake from those snacks. Outcomes were identical for grams of snack food consumed by participants, regardless of package unit size. However, amount of food (portion size) was found to have a significant effect on food intake. Participants in the large amount condition ate a significantly greater quantity of food than those in the small amount condition (9). Although the results from this study suggest that package unit size does not influence food intake, this could be related to the fact that participants recruited for this study were dietary unrestrained and primarily normal

weight. Individuals with these characteristics may not be concerned with monitoring their food intake and thus, package unit size may not impact food intake through the mechanism of increased consumption monitoring accuracy in these individuals (9, 10, 14, 15, 28).

Studies Investigating Package Unit Size and Food Intake

By packaging food in an amount that provides a smaller unit of food, particularly in the unit size of a more standard serving size, certain individuals may be able to better monitor the amount of food they consume and therefore, limit their overall energy intake (9, 10, 14). Little research has been conducted in this area and the findings of research that has been conducted in this area are inconsistent (9, 10, 14, 15, 28, 29). This inconsistency could be related to differences in weight status and level of dietary restraint among participants in the various studies. More specifically, overweight status and/or high dietary restraint status may interact with package unit size through the mechanism of increased consumption monitoring accuracy to influence one's food intake, while normal weight status and/or low dietary restraint status may have no such interaction with package unit size (5, 9).

Highlighting this inconsistency in the literature are the results from a study conducted in a non-laboratory setting by Freedman and Brochado (28), which are in stark contrast to the findings of the Raynor and Wing (9) study previously mentioned. Although this study states that it investigated the impact of reductions in portion size, the term "portion size" used by these researchers actually refers to the package unit size of French fries served to individuals in an all-you-can eat environment. To as great a degree as possible, the amount of French fries available in the environment was held constant throughout the study. However, as this study was conducted in an all-you-can eat dining facility, results should be viewed with caution because the overall amount of French fries available in the environment was less-controlled as compared to

lab-based studies. Also, because this study was performed in a natural eating environment under less-controlled settings, participant characteristics, such as weight status and level of dietary restraint were not described. In this investigation, French fries were offered at a university dining facility in individual paper bags, initially in a unit size of 88 g. The unit size decreased by 15 g per week for three consecutive weeks. Because the packages of French fries were served at an all-you-can-eat dining facility, diners were allowed to serve themselves more than one bag of French fries. Intake of French fries per diner was measured by dividing the total amount of French fries consumed by the total number of diners choosing French fries from the serving line. Total amount of French friends consumed was measured by subtracting plate waste from the amount of French fries produced (28). This investigation found that as package unit size decreased from 88 to 44 g, a significant reduction in intake of French fries per diner occurred.

Stroebele and colleagues (10) conducted a randomized cross-over study to investigate the effects of decreasing package unit size on food intake when the amount of food provided was held constant. In this study, primarily overweight participants (mean Body Mass Index [BMI] of 27.7) deemed as frequent snackers (2+ snacks/day) received either 100 kcal snack packages or standard size packages to take home for one week, followed by a washout period and subsequent receipt of the other snack unit size to take home for one week. To ensure adequate amount of food was available for consumption during the 1-week snack period, four packages of the standard size snacks (ranging in weight from 187 g to 368.5 g each) were given during the week designated for the standard size package experimental condition. During the week designated for the 100 kcal snack package experimental condition, the number of snack packages (ranging in weight from 19.2 g to 26 g) given to participants was consistent with the gram weight of snacks provided in the standard size package condition. Overall, participants ate significantly less

(186.9 g less per week) when given the 100 kcal snack packages compared to the standard package size.

Supporting the idea that individual characteristics do moderate the relationship between food package unit size and intake, Wansink and colleagues (14) found that weight status (specifically, overweight status) interacts with package unit size to influence food intake. In this study, thirty-seven normal weight and overweight undergraduate students randomly received either four 100-calorie packages of crackers or one 400-calorie package of crackers to consume while watching television in a laboratory setting. Total amount of crackers was held constant across each condition. In this study, there was a main effect of package size, in which both normal weight and overweight participants ate about 25% less from the 100-calorie packages than from the 400-calorie package. Results of the study also found an interaction, such that overweight participants consumed an average of 208 calories more from the 400-calorie package than from the 100-calorie packages of crackers. No such relationship was found, however, between package unit size and food intake for normal weight participants. Furthermore, it was found that, while not significant, overweight participants ate more calories from the one large package than normal weight participants, consuming on average 130 calories more. Level of dietary restraint was not measured in this study, so it remains to be determined whether this participant characteristic may interact with package unit size to impact food intake.

Additionally, Raynor and colleagues (15) investigated the effects of providing breakfast foods in single-serving packages and standard packages on intake of these food provisions during a brief behavioral weight-loss intervention. Total amount and type of food (cereal and peaches; applesauce and cheese) were held constant across conditions; only unit size of food was manipulated. Overweight and obese participants were randomized to either a single-serving

package condition or a standard package condition, in which they received corresponding packages of foods to eat at breakfast for the eight weeks of the intervention. Participants in both groups were told to monitor their food intake by eating only one serving of the provided foods for breakfast daily. Participants in the single-serving package condition had the food pre-portioned into the amount they should consume daily for breakfast, while participants in the standard package condition had to measure out a single serving from standard packages. Results of the study demonstrated that those in the single-serving package condition ate significantly less energy from the provided foods, particularly the cereal and applesauce (80.2 versus 106.3 kcal/day and 44.5 versus 59.3 kcal/day, respectively), as compared to the standard package condition. Because the participants in this study were reducing energy intake as part of the program they were participating in, they could also be classified as restrained eaters and thus, this study provides support that level of dietary restraint may interact with package unit size to influence food intake.

Although these studies show that package unit size has an impact on food intake, some studies have demonstrated that package/food unit size has no significant effect on food intake. As mentioned earlier, Raynor and Wing (9) found that regardless of package unit size, snack food consumption (in terms of gram weight) among participants was identical. Similar to this study, Devitt and colleagues (29) found no significant effect of food unit size on food intake when normal weight/overweight participants were given small food units compared to customary food units. Although weight status was reported in this study, level of dietary restraint was not described. Consistent with other package unit size studies, amount of food available for consumption was held constant; only the food unit size was manipulated. Twenty-six participants ate breakfast (omelets), lunch (wrap sandwiches), and dinner (pizzas) in the

laboratory on four separate days, and meals were divided into either small or customary food units on the days designated for those experimental conditions. Analysis of the study results showed that gram weight consumed did not differ across the treatments, thus participants ate a reasonably constant weight of food regardless of unit size (29). Statistical analyses found no correlation between participant weight status and the relationship between package unit size and gram weight of food consumed. Thus, it seems that weight status did not interact with package unit size to influence food intake. The effect of dietary restraint on the relationship between package unit size and food intake could not be investigated as this participant characteristic was not measured by the investigators.

The contrasting results of these studies investigating the relationship between package unit size and food intake could be related to differences in participant variables, particularly weight status and level of dietary restraint. Only one of the above studies investigated the independent effects of weight status (normal weight; overweight) on the relationship between package unit size and food intake (14), and none of the above studies investigated the independent effects of the level of dietary restraint (unrestrained; restrained) on this relationship. Furthermore, no studies investigated the combined effects of these two participant characteristics on the relationship between package unit size and food intake. Thus, it remains unknown whether the inconsistent results observed in the studies could be related to differences in weight status and level of dietary restraint among participants.

CONCLUSION

Summary

In summary, much of the research investigating the independent effects of portion size and package unit size on food intake combined the dietary environmental variables, portion size

and package unit size (6-8, 22, 25, 26). As studies began to tease these dietary environmental factors apart, research results demonstrated that perhaps portion size does not interact with individual characteristics (weight status and dietary restraint) to influence food intake, while package unit size may interact with such characteristics to influence food intake (9, 14, 15). Results of studies investigating portion size and food intake are consistent and show an increase/decrease in food intake with an increase/decrease in portion size, independent of differences among participant characteristics in the various studies (7, 12, 13). This supports the idea that portion size of food affects food intake regardless of weight status or level of dietary restraint. Thus, people, in general, tend to eat more when a larger amount of food is presented to them because it serves as a consumption norm or a cue for increased energy intake. In contrast, individual characteristics, such as weight status and level of dietary restraint, may interact with the package unit size of food to influence food intake (9, 10, 14, 15). Therefore, it is thought that the mixed results of the studies investigating package unit size and food intake could be related to differences in participant weight status and level of dietary restraint. It has been proposed that overweight individuals or restrained eaters may more closely monitor their food intake (9). In such cases, smaller package unit sizes of food may increase the accuracy of consumption monitoring and thus, help control food intake. Normal weight, unrestrained participants may not be concerned with monitoring their food intake and thus, package unit size may have no significant effect on the food intake of these individuals (9). Studies conducted in this area of research have recruited participants with varying degrees of weight status and levels of dietary restraint. Therefore, differences in weight status and level of dietary restraint among participants in the above studies could account for the inconsistent results observed.

To date, no studies have investigated the impact of these individual characteristics, separately and in combination, on the relationship between package unit size and food intake. A better understanding of the relationship between package unit size and food intake will help professionals determine if this is an effective tool to assist with food intake reduction and if so, to which individuals this dietary tool can best be applied.

Specific Aims

Therefore, the objective of this study was to determine the independent and combined effects of weight status and the level of dietary restraint on the relationship between package unit size and food intake. Sixty-four participants were classified into four groups based on weight status and level of dietary restraint: normal weight, unrestrained; normal weight, restrained; overweight, unrestrained; and overweight, restrained. Participants in each of these four groups were then randomly assigned to receive either single-serving pretzel packages or standard size pretzel packages (a total of eight groups in all). Participants in each group were given a box of pretzels, corresponding to their respective snack package condition, to take home for four days and consume ad libitum. After the 4-day study period, participants brought all snack packages back to the laboratory (unopened, opened, or emptied). Total grams of pretzels consumed was determined by subtracting pre- and post-consumption weight of snack packages provided.

Comparisons were then made between groups in order to address the following specific aims:

1. Determine the effect of dietary restraint on the relationship between package unit size and food intake.
2. Determine the effect of weight status on the relationship between package unit size and food intake.

3. Determine the combined effect of weight status and dietary restraint on the relationship between package unit size and food intake.

CHAPTER II
MANUSCRIPT

INTRODUCTION

The estimated prevalence of obesity among adults in 2007-2008 was 33.8% and the combined estimated prevalence of overweight and obesity was 68.0% (1). Although the etiology of the current obesity epidemic remains unknown, there is a general consensus that environmental dietary factors, such as large portion and large package unit size, encourage excessive food intake and positive energy balance (4, 5).

Much of the research investigating how portion size and package unit size of food affects energy intake have treated these variables as one, rather than separate variables (6-8, 12, 13, 22-26). In these studies, as portion and unit size increases, so does intake (6-8, 12, 13, 22-26). Thus, it is unclear in these studies whether the effect on consumption was due to the portion size, the unit size, or both the portion and the unit size of food presented to the individual. For example, Rolls and colleagues (6-8, 12, 13) conducted a number of studies in controlled laboratory settings and repeatedly found that larger portion sizes/unit sizes led to increases in energy intake. In two such studies, Rolls and colleagues (12, 13) looked at the effect on overall energy intake when portion sizes/unit sizes were increased over the course of two and eleven consecutive days, respectively. It was discovered that increases in food portion size/unit size led to increases in energy intake and that compensation for increased intake did not occur at later meals. Studies conducted in natural settings also found that larger portion sizes/unit sizes promote greater energy intake (22, 25, 26). In two studies conducted by Wansink and colleagues (25, 26), it was found that moviegoers ate significantly more popcorn from large containers than from medium ones.

To better understand the influence of portion and package unit size on consumption, it is important to examine these variables separately, as it is believed that these variables may

influence consumption through different mechanisms (4, 5, 9). Portion size (defined as the amount of food available in the environment) is hypothesized to affect food intake by suggesting consumption norms or by serving as a cue to eat (5, 9-11). Package unit size of food may influence food intake by impacting the accuracy of consumption monitoring (4, 5, 9).

For individuals who frequently engage in consumption monitoring, package unit size may be of importance because large packages may decrease the accuracy of consumption monitoring by making it difficult to assess how many servings have been consumed in one sitting, while small, single-serving packages may increase the accuracy of consumption monitoring by providing a clear definition of what a standard serving is and how much one has consumed (5, 9, 10). Individual characteristics, such as weight status and dietary restraint, may moderate the degree of occurrence of consumption monitoring, which in turn could impact the influence of package unit size on food intake. Specifically, overweight and/or dietary restrained individuals may engage in consumption monitoring more so than non-overweight and/or dietary unrestrained individuals. While it might seem obvious that restrained individuals (those who closely monitor and tightly control amount of food consumed) may engage in consumption monitoring more so than unrestrained individuals, it might not seem so obvious why overweight individuals may engage in consumption monitoring more so than non-overweight individuals. Some studies, however, have shown that overweight individuals are more likely to rely on external cues than normal weight individuals (30, 31). Thus, overweight individuals may rely more so on external cues to stop eating, such as finishing a bag of pretzels, than normal weight individuals (30, 31).

Interestingly, studies solely investigating package unit size and food intake have produced inconsistent findings (9, 10, 14, 15, 28, 29), which may be a consequence of the hypothesized moderating variables (weight status and dietary restraint). In studies conducted by

Freedman and Brochado (28) and Stroebele and colleagues (10), it was discovered that reductions in package unit size led to decreases in food intake; however, weight status and/or restraint status were not reported on in these studies. In a study conducted by Wansink and colleagues (14), it was found that weight status, specifically overweight status, interacted with package unit size to influence food intake, such that overweight participants ate significantly more calories (average of 208 calories more) when eating from one, 400-calorie package than from four, 100-calorie packages. Additionally, in a study conducted by Raynor and colleagues (15), it was found that participants who could be classified as restrained eaters ate significantly less energy from single-serving packages compared to standard packages. In contrast to the above results, Devitt and colleagues (29) found no significant effect of food unit size on food intake. Participants in this study were normal weight and overweight. Restraint status was not reported. Consistent with the results of the study by Devitt and colleagues (29), Raynor and Wing (9) also found that package unit size had no effect on consumption; however, participants in this study were primarily normal weight and dietary unrestrained.

To date, only one study has investigated the independent effect of weight status on the relationship between package unit size and food intake (14), and no study has investigated the independent effect of dietary restraint status on this relationship. Furthermore, no studies have investigated the combined effects of these two participant characteristics on the relationship between package unit size and food intake. Thus, it remains unknown whether the inconsistent results observed in studies investigating package unit size and food intake could be related to differences among participants in weight status, dietary restraint status, or both. Therefore, the objective of this study was to determine the independent and combined effects of weight status and the level of dietary restraint on the relationship between package unit size and food intake. It

was hypothesized that single-serving packages would aid both overweight and dietary restrained individuals in the act of consumption monitoring and thus, would allow these individuals to limit their food intake as compared to standard size packages. Additionally, it was hypothesized that this effect would be most pronounced in individuals classified as both overweight and dietary restrained.

EXPERIMENTAL DESIGN & METHODOLOGY

Study Design

This study used a 2x2x2 between-subjects factorial design, with the between-subject factors of weight status (normal weight versus overweight), restraint status (unrestrained versus restrained), and package unit size (single-serving versus standard) (see Appendix A Table 1). This study was quasi-experimental in that participants were non-randomly assigned to groups based on weight and dietary restraint status. However, for the between-subject factor of package unit size, participants were randomly assigned to receive either the single-serving package condition or the standard size package condition. Total grams of the provided food (pretzels) consumed was the primary dependent variable and was calculated by subtracting pre- and post-consumption weight of snack packages provided. This study was approved by the Institutional Review Board (IRB) at The University of Tennessee, Knoxville (UTK) and was registered with ClinicalTrials.gov (Identifier: NCT01384552).

Participants

Participants were recruited from the UTK campus area. Flyers describing the study were posted around campus and e-mails with an attached flyer were sent out to UTK academic department list-servs. Additionally, flyers were posted in local health clubs, fitness centers, and parks. This study recruited participants using a rolling enrollment strategy. Interested

individuals were asked to contact the Healthy Eating and Activity Laboratory (HEAL) for an initial phone screening to determine eligibility prior to study enrollment. Prospective participants were told that the purpose of the study was to investigate the effects of recent snack food consumption on liking of snack foods. Upon completion of the phone screening, those who were deemed eligible were scheduled for an initial session, where they signed a consent form (approved by the UTK IRB).

Sample Size

To examine the influence of weight status and the level of dietary restraint on the relationship between package unit size and food intake, sixty-four participants were needed. Sample size calculations assumed a 2-tailed statistical test with an alpha (type I error rate) equal to 0.05. Based on results from a recent study conducted by Wansink and colleagues (14), the calculated effect size for weight for this study was 1.94. Thus, to detect an effect of this size with 80% power, a minimum of eight participants per group, yielding a total sample size of sixty-four participants, was needed.

Eligibility Criteria

Eligibility for this study was based upon the following criteria:

- 1) Male and females aged 18-35 years old.
- 2) BMI between 18.5-24.9 kg/m² or BMI between 25.0-39.9 kg/m².
 - a. For normal weight groups: BMI of 18.5-24.9 kg/m².
 - b. For overweight groups: BMI of 25.0-39.9 kg/m².
- 3) Dietary restraint scores of either ≤ 12 or > 12 on the Three Factor Eating Questionnaire-Cognitive Restraint scale (TFEQ-R) (17).
 - a. For unrestrained groups: ≤ 12 .

- b. For restrained groups: > 12.
- 4) Did not have unfavorable preference toward pretzels.
- 5) Did not have allergies to pretzel ingredients.
- 6) Did not have a health condition or use medication that affected eating or required a therapeutic diet.
- 7) Had a consistent schedule during the time of the study.
- 8) Agreed to instructions to not share pretzel snack packages with others.

Participants were excluded from the study based upon the following criteria:

- 1) BMI below 18.5 or above 39.9 kg/m².
- 2) Had an unfavorable preference toward pretzels.
- 3) Had allergies to pretzel ingredients (wheat flour).
 - a. Severe allergies to nuts – Snyder's® of Hanover pretzels are made in a facility that handles peanut butter.
- 4) Were unwilling to consume pretzels during the time of the study.
- 5) Were pregnant or breastfeeding.
- 6) Did not meet one or more of the other above mentioned eligibility requirements.

Recruitment

From June 2011 to October 2011, 165 individuals expressed interest in participating in the study and were phone screened, with 98 individuals not meeting eligibility criteria.

Individuals were excluded from the study based on the following reasons: 7 individuals disliked pretzels; 5 individuals were either older or younger than the required age range of 18-35 years; 4 individuals were either above or below the required BMI range of 18.5-39.9 kg/m²; 1 individual had a health condition that required a therapeutic diet; 1 individual could not have her height

properly assessed for BMI calculations; 1 individual had familiarity with the research; 1 individual did not know what pretzels were and had never tasted them; 2 individuals moved away prior to their scheduled sessions; 2 individuals did not show up for their scheduled sessions and could not be rescheduled; and 74 individuals' BMI and TFEQ-R scores placed them in a category that had already met enrollment limit. A total of 67 individuals completed the study, with three participants excluded from the study after the second session. Of these three participants, one failed to bring back all pretzels packages, while two participants ate all of the pretzels provided to them. Exclusion of such participants is common protocol in basic eating studies (32). After the above mentioned exclusions, 64 participants remained and successfully completed all aspects of the study.

Procedure

Following completion of the initial phone screen, participants were grouped based on dietary restraint classification (unrestrained eater versus restrained eater) and weight status classification (normal weight versus overweight). Based upon these groupings (four in all), participants were randomly assigned (using a random number generator) to either the single-serving package unit size condition or the standard package unit size condition, giving a total of eight groups. Eligible participants were scheduled for a 30-minute individual session on Thursdays or Fridays at the HEAL. During this initial session, informed consent was obtained, height and weight was measured, and participants rated their liking of pretzels on a 100-mm Visual Analog Scale (VAS).

At this initial session, participants were also given either a box of single-serving pretzel packages or a box of standard size pretzel packages corresponding to their randomly assigned package unit size condition. Participants were informed that they were to take home the box of

pretzels for a period of four days and then return the box of pretzel packages to the HEAL at a second session. Participants were instructed to bring back all snack packages of pretzels, including packages that had been opened or emptied. Participants were informed that during this 4-day period, they would need to refrain from sharing the provided pretzels with others and would need to at least taste the pretzels, but could eat as little or as much as they desired. In addition, participants were given a brief form to fill out during the study period documenting when (date/time) and where they consumed the provided pretzels. Participants were not asked to record amount consumed. Prior to leaving, participants were reminded of the date and time of their second 10-minute session that they had to attend four days from the initial session.

At the second session, participants brought back all pretzel packages, including packages that had been opened or emptied. In addition, participants brought back the completed form documenting when (date/time) and where they consumed the provided pretzels. Participants were asked if anyone other than themselves had consumed the provided pretzels over the 4-day study period. In order to fulfill the original purpose of the study as it was presented to participants (the participants were told that they were being recruited for a study regarding the effects of recent snack food consumption on liking of snack foods), participants were once again asked to rate their liking of pretzels on a 100-mm VAS. Following this last measurement, participants were debriefed, compensated, and thanked for their participation.

Compensation

Upon completing the food study and attending the second session (including turning in all pretzel packages and the accompanying self-report of pretzel consumption form), participants were compensated \$10.00 for their efforts and involvement in this study.

Pretzel Package Unit Size

Pretzel packages were provided in either a single-serving package unit size (0.9 oz.) or a standard package unit size (10.0 oz.). Participants received one box of either the single-serving Snyder's® of Hanover pretzel packages or the standard Snyder's® of Hanover pretzel packages corresponding to their randomly assigned package unit size condition. Pretzels were provided to participants in the food manufacturer's original packaging. To keep amount of food provided consistent (so that only package unit size was manipulated), boxes containing the single-serving size packages had twenty-two, 0.9-oz. packages of pretzels, and boxes containing the standard size packages had two, 10.0-oz. packages of pretzels.

Measures

Basic demographic information (age, sex, education, marital status, race, and ethnicity) was assessed at entry into the study.

Anthropometrics

Participant height and weight was gathered via self-report during the initial phone screening. Participant height and weight was also assessed during the first session using a portable stadiometer and an electric scale, respectively. Measurements were made according to standard procedures (33). Height was recorded to the nearest one-eighth inch and weight was recorded to the nearest one-tenth pound. BMI was calculated by dividing the weight in kilograms by height in meters squared.

Dietary Restraint

During the initial phone screening, the level of dietary restraint was determined using the TFEQ-R (17). The TFEQ has previously been shown to be valid and reliable in measuring three dimensions of eating behavior: dietary restraint, disinhibition, and hunger (17). The TFEQ-R, a

21-item factor, measures dietary restraint on a scale of 0-21, with 0 being a completely unrestrained eater and 21 being a completely restrained eater (17). A maximum of one point is awarded per item. Items include true/false statements, as well as close-ended questions. Participants scoring ≤ 12 were classified as an unrestrained eater, while participants scoring > 12 were classified as a restrained eater.

Liking of Pretzels

Participants rated their degree of liking of pretzels both at the first and second session using a 100-mm VAS. This scale used the anchors of “extremely dislike” on the left and “extremely like” on the right.

Location of Pretzel Consumption

At the first session, participants in both groups were given a brief form to fill out during the 4-day study period, documenting when (date/time) and where they consumed the provided pretzels. Participants returned the completed form at the second session. This was done to assess whether pretzel consumption from single-serving packages was related to a convenience factor. For example, if pretzel consumption was related to a convenience factor, then individuals may have consumed pretzels from small, single-serving packages because they were easily transported from one place to another (as compared to standard size packages). Therefore, if participants were consuming more pretzels outside of the home, it might indicate they were doing so out of convenience. To detect whether pretzel consumption from single-serving packages was related to a convenience factor, percentage of pretzel consumption occurring outside the home was calculated for each participant by dividing the number of times pretzels were consumed outside of the home by the total number of times pretzels were consumed (at home and outside the home) and then multiplying by 100.

Measured Pretzel Consumption

Pretzels provided to participants in each condition were measured in the Snyder's® of Hanover original packaging on an electronic food scale (Denver Instrument Co., Arvada, CO) before giving them to participants to take home for four days. At the second session, all pretzel packages, including those that had been opened or emptied, were once again measured using the same electronic scale. Total grams of pretzels consumed was determined by subtracting pre- and post-consumption weight of snack packages provided.

Statistical Analyses

A 2x2x2 (unrestrained/restrained x normal weight/overweight x single-serving package/standard size package) analysis of variance (ANOVA) and Chi-square tests were performed to analyze differences between the groups in baseline characteristics relevant to the investigation, such as BMI, dietary restraint scores, age, hedonic ratings of pretzels, gender, marital status, education, and race/ethnicity. For numerical data (BMI, dietary restraint scores, age, hedonic ratings of pretzels), ANOVAs were used. Chi-square tests were performed for categorical data (gender, marital status, education, race/ethnicity). A 2x2x2 ANOVA was used to determine if percentage of pretzel consumption occurring outside the home was different between the groups. To analyze differences between the groups on the primary outcome measure of total grams of pretzels consumed, a 2x2x2 ANOVA was also performed. Post hoc pairwise comparisons with Bonferroni adjustments were made for significant outcomes ($p < 0.05$) to determine exactly which groups differed. All statistical analyses were performed using SPSS Statistics 19.0 (34), with significance level set at 0.05.

The effect size for significant results between groups on the primary outcome measure of total grams of pretzels consumed was calculated using G Power (35). Effect size was calculated

as Cohen's *d* using means and standard deviations of total grams of pretzels consumed. Effect sizes were calculated as small (0.2), medium (0.5), or large (0.8) (36).

RESULTS

Participant Characteristics

Baseline characteristics of participants are shown in Appendix A Table 2. The participants were predominantly white (81.3%), non-Hispanic (96.9%), and had never been married (70.3%). The majority of participants had either completed some college (42.2%) or had already acquired a college/university degree (35.9%). There were no significant differences between groups for these baseline characteristics.

As weight and restraint status were between-subject variables, as anticipated, significant differences in BMI and restraint scores occurred based upon group categorizations. For BMI, a significant main effect of weight status ($F(1,56) = 97.4, p < 0.001$) occurred, where those who were normal weight had a significantly lower BMI ($22.2 \pm 1.4 \text{ kg/m}^2$) compared to those who were overweight ($29.8 \pm 4.1 \text{ kg/m}^2$). For restraint scores, there was a significant 3-way interaction between weight status, package unit size, and restraint status ($F(1,56) = 6.4, p < 0.05$). Pairwise comparisons showed that normal weight participants randomized to the standard size condition had significantly ($p < 0.05$) lower restraint scores (10.1 ± 5.7) compared to overweight participants randomized to this same condition (12.1 ± 3.8). For normal weight and overweight participants randomized to the single-serving condition, there was no significant difference in restraint scores between these two weight classifications (11.5 ± 4.1 and 11.6 ± 6.0 , respectively). Additionally, a significant main effect of restraint status ($F(1,56) = 156.6, p < 0.001$) occurred, where those who were classified as unrestrained eaters had a significantly lower restraint score (7.2 ± 3.3) compared to those who were classified as restrained eaters (15.4 ± 2.0).

The above findings were to be expected due to the focus on weight and restraint status classifications for appropriate group categorization in this study.

For age, there was a significant main effect of weight status ($F(1,56) = 4.5, p < 0.05$), in which those who were overweight were older (24.6 ± 3.9 years) than those who were normal weight (22.9 ± 2.4 years). Additionally, there was a significant main effect of restraint status ($F(1,56) = 5.2, p < 0.05$), in which those who were restrained were older (24.6 ± 3.2 years) than those who were unrestrained (22.8 ± 3.2 years). For gender, a significant difference ($X^2(7) = 17.8, p < 0.05$) was found between normal weight, restrained participants randomized to the single-serving condition (12.5% male; 87.5% female) and overweight, unrestrained participants randomized to the standard size condition (100.0% male; 0.0% female). For first session hedonic ratings of pretzels, there was a significant interaction between package unit size and restraint status ($F(1,56) = 4.8, p < 0.05$). Pairwise comparisons revealed that unrestrained eaters randomized to the single-serving condition had a significantly ($p = 0.073$) higher degree of liking for pretzels (70.4 ± 10.6 mm) as compared to unrestrained eaters randomized to the standard size condition (63.6 ± 10.4 mm). For restrained eaters randomized to the single-serving and standard size conditions, there was no significant difference in degree of liking for pretzels between these two conditions (63.9 ± 10.9 and 68.7 ± 9.4 mm, respectively).

Spearman correlations were conducted to assess if the above baseline characteristics were significantly related to the percentage of times pretzels were consumed outside the home and to the total grams of pretzels consumed. Because none of these baseline characteristics were found to be significantly related to these future measures of interest, they did not need to be included as covariates in subsequent analyses. Analyses, however, were conducted with and without these variables included as covariates.

Location of Pretzel Consumption

Spearman correlations revealed that none of the baseline characteristics found to be statistically different between groups (age, first session hedonic ratings of pretzels, and gender) were significantly ($p > 0.05$) related to the measure of percentage of times pretzels were consumed outside the home. Analyses, both including baseline characteristics that were significantly different between the groups (age, first session hedonic ratings of pretzels, and gender) as covariates and not including these variables as covariates, revealed that no significant ($p > 0.05$) interactions or main effects occurred for the percentage of times pretzels were eaten away from home. Percent of pretzel consumption occurring outside of the home for participants randomized to the single-serving package unit size condition was $53.6 \pm 32.9\%$, while percent of pretzel consumption occurring outside of the home for participants randomized to the standard package unit size condition was $44.3 \pm 37.1\%$. Results for the percentage of times pretzels were eaten outside the home by groups are displayed in Appendix A Figure 1.

Measured Pretzel Consumption

Spearman correlations revealed that none of the baseline characteristics found to be statistically different between groups (age, first session hedonic ratings of pretzels, and gender) were significantly ($p > 0.05$) related to the primary dependent variable of total grams of pretzels consumed. Analyses, both including baseline characteristics that were significantly different between the groups (age, first session hedonic ratings of pretzels, and gender) as covariates and not including these variables as covariates, revealed that there was a significant interaction between package unit size and weight status ($F(1,56) = 7.1, p = 0.01$). Pairwise comparisons showed that overweight participants randomized to the standard size condition ate significantly ($p < 0.05$) more grams of pretzels (204.4 ± 144.9 g) compared to overweight participants

randomized to the single-serving condition (107.0 ± 101.9 g). The effect size between these groups was $d = 0.78$, a medium-to-large effect size. For normal weight participants randomized to the single-serving and standard size conditions, there was no significant ($p > 0.05$) difference in total grams of pretzels consumed between these two conditions (158.1 ± 104.4 and 112.7 ± 58.9 g, respectively). Additionally, pairwise comparisons revealed that for participants randomized to the standard size condition, overweight participants ate significantly ($p < 0.05$) more grams of pretzels (204.4 ± 144.9 g) than normal weight participants (112.7 ± 58.9 g). The effect size between these groups was $d = 0.83$, a large effect size. For normal weight and overweight participants randomized to the single-serving condition, there was no significant ($p > 0.05$) difference in total grams of pretzels consumed between these two weight classifications (158.1 ± 104.4 and 107.0 ± 101.9 g, respectively). No other significant ($p > 0.05$) interactions or main effects of weight status, package unit size, or restraint status were found. Results for the primary outcome measure of total grams of pretzels consumed are presented in Appendix A Figure 2 and Figure 3.

DISCUSSION

The purpose of this study was to determine the independent and combined effects of weight status (normal weight versus overweight) and the level of dietary restraint (unrestrained versus restrained) on the relationship between package unit size and food intake in sixty-four young males and females in a natural eating environment. It was hypothesized that single-serving packages would assist individuals classified as either overweight or dietary restrained in limiting their food intake as compared to standard size packages. Additionally, it was hypothesized that this effect would be most marked in those classified as both overweight and dietary restrained. Results from this study, however, showed that standard size packages

influenced overweight participants to eat significantly more grams of pretzels as compared to single-serving packages when amount of food was held constant. Overweight participants ate 204 grams of pretzels on average from standard size pretzel packages, while an average of only 107 grams of pretzels was consumed by overweight participants from single-serving packages. No such effect of package unit size on food intake was observed for normal weight participants. Additionally, overweight participants ate significantly more grams of pretzels from standard size packages than normal weight participants, consuming on average 92 grams more. Gram intake of pretzels from single-serving packages did not significantly differ between normal weight and overweight participants. Thus, for overweight participants, the standard package unit size appeared to increase consumption as compared to both single-serving packages given to overweight participants and standard size packages given to normal weight participants.

The finding that larger, standard size packaging increases intake in overweight individuals appears, at first glance, to be contradictory to previous research by Wansink and colleagues (14). In this study, Wansink and colleagues (14) concluded that sub-packaging (packaging food into four, 100-calorie packages versus one, 400-calorie package) significantly reduced the amount of food overweight participants consumed. Participants, both normal weight and overweight, in this study ate about 25% less from the 100-calorie packages than from the 400-calorie package (14). Thus, there was a main effect of package unit size. However, simple effects analyses actually demonstrated that overweight participants consumed significantly more from the one, 400-calorie package than from the four, 100-calorie packages (208 calories more); there was no significant difference in caloric intake between package unit size conditions for normal weight participants (14). Additionally, it was revealed that, while not significant, overweight participants consumed an average of 130 calories more from the 400-calorie package

than normal weight participants consumed from the same package unit size. Thus, it seems quite plausible that for overweight participants, the larger packaging in Wansink's study (14) may have encouraged increased consumption more so than the smaller packaging encouraged decreased consumption, similar to the findings of this investigation.

The similarities between the findings of these two studies are noteworthy because each was conducted under different settings. The present study was conducted in a natural eating environment, whereby participants were allowed to take the pretzel packages home with them for a 4-day period. This provided external validity by closely mimicking what would occur in a real world situation. In contrast, Wansink's study (14) was conducted in a controlled, laboratory setting, lending internal validity to the study.

It was hypothesized that package unit size may interact with weight status to influence food intake because overweight individuals may more closely monitor their food intake compared to their normal weight counterparts. Packaging food into small, single-serving packages may, therefore, increase the accuracy of consumption monitoring for these individuals, thus helping to further control food intake (9,15). The results of the present study, however, do not support this hypothesis. Overweight individuals did not consume a significantly less amount of food from single-serving packages as compared to normal weight individuals. Thus, it does not seem that consumption monitoring accuracy was increased and that this increase led to a reduction in consumption volume. The finding that the standard size packages increased food intake for overweight individuals as compared to normal weight individuals points to another mechanism that may be influencing eating behaviors. Schachter's (37) externality theory proposes that overweight/obese individuals are highly responsive to external cues, which prompt these individuals to eat until the external cues are removed. Relating this to the present study,

overweight individuals were highly responsive to the larger package unit size, thus encouraging these individuals to eat significantly more than normal weight individuals, who were relatively unresponsive to package unit size. Because overweight individuals may be more responsive to external cues, it seems logical that removing such cues would provide a solution to overeating.

However, it must be noted that studies investigating the effect of portion size on food intake have demonstrated that people, regardless of weight or restraint status, tend to eat more when a larger amount of food is presented to them because it serves as a cue or a consumption norm (6-9, 12, 13). If package unit size also affects food intake by serving as a cue, why does it not produce an effect in normal weight participants, as it does in overweight participants? The answer might be found in how overweight participants serve themselves from a package during an eating occasion. If, for example, overweight individuals, who are overly responsive to external cues, eat directly from a large package, the external cue to overeat may be heightened. If, however, overweight individuals take only a serving out of a large package and then put the large package away, the external cue to eat has been reduced, thus limiting the likelihood of overeating. The same holds true for normal weight participants. If normal weight participants eat directly from a large package, the external cue to overeat may be heightened, as well. Thus, the effect of large packaging on consumption volume for overweight individuals and not normal weight individuals could be attributed to the fact that overweight individuals may serve themselves from large packages differently than normal weight individuals. Overweight individuals may eat directly from large packages, prompting overconsumption, while normal weight individuals may take only a serving out of a large package and then put the large package away. Additional research is needed to determine how individuals, both normal weight and

overweight, serve themselves from larger packages, thus helping to further elucidate the mechanism through which package unit size influences food intake in these individuals.

To accurately interpret the above results, it was necessary to detect whether participants were eating from single-serving packages due to an added level of convenience. Because single-serving packages are easily transported from one place to another (as compared to standard size packages), more pretzel consumption outside the home might indicate that pretzel consumption from these packages was occurring due to a convenience factor. Results of participant self-report of pretzel consumption forms, however, indicated that pretzel consumption was not influenced by location (home versus outside the home).

Restraint status did not interact with package unit size to impact food intake in the current investigation. It has been proposed that because restrained eaters closely monitor and control the amount of food they consume, single-serving packages may assist with the act of consumption monitoring and thus, may help control or reduce one's food intake (9). This, however, did not seem to occur in the present study. Restrained and unrestrained participants had similar reductions in amount consumed from single-serving packages as compared to standard size packages. As with the above findings related to weight status, these similarities in decreased consumption volume do not indicate that smaller package unit sizes help to increase consumption monitoring accuracy, thus helping to control or reduce food intake for restrained individuals compared to unrestrained individuals. One explanation for this finding could be that plain, salted pretzels are not generally considered to be a highly palatable, energy-dense snack food that is consumed in large quantities. Restrained participants may not have viewed pretzels as a problematic snack food that needed to be restricted and thus, may have engaged in similar eating habits as their unrestrained counterparts. Had this investigation used another snack food,

such as chips, candy, or cookies, the results may have been more striking. More specifically, if such snack foods were used, restrained participants may have consumed much less food from single-serving packages than from standard size packages, as well as consumed much less food compared to unrestrained participants, because of the fact that these individuals would have been more concerned with monitoring the amount of food they were consuming. Additional research is needed to explore this hypothesis.

Although this study had several notable features, such as use of objective measures for determining total grams of pretzels consumed, examination of whether pretzel consumption from single-serving packages was related to a convenience factor, and use of naturalistic eating conditions to increase external validity, there were also a few limitations. The study included predominantly non-Hispanic, white participants with an average age of 24. The homogenous sample size restricts the overall generalizability of the results to other groups with differing characteristics. Also, because the study was conducted in a natural eating environment, internal validity of the study was reduced. Although participants were instructed not to share the pretzels with others, it cannot be determined for certain that this occurred. Another limitation is that participants were not asked to record the types and amounts of food consumed over the study period. Had participants kept a food record over the study period, the effects of any added food consumption on total gram intake of pretzels could have been ascertained. A final limitation is that a between-subjects design, rather than a within-subjects design, was used for this study in order to prevent participants from discovering the true purpose of the investigation.

Despite these limitations, the results from this study provide a better understanding of the relationship between package unit size and food intake. Weight status, particularly overweight status, did significantly interact with package unit size to influence food intake, while restraint

status did not. Additionally, there was no combined effect of weight status and restraint status on the relationship between package unit size and food intake. Future research should look at the effect of using different types of packaged food, such as chips, candy, or cookies, as well as investigate the mechanism through which package unit size influences food intake in overweight individuals. Additionally, it would be important to look at how individuals, both normal weight and overweight, serve themselves from large packages.

Overall, the results from this study suggest that for overweight individuals, large, standard size packages produce greater consumption as compared to single-serving packages. While single-serving packages may not influence overweight individuals to eat less in comparison to normal weight individuals, single-serving packages may still be advantageous for this population group. Because overweight individuals may be overly responsive to larger package sizes, prompting overconsumption, single-serving packages may remove an external cue to overeat. Therefore, single-serving packages, while not helping to reduce intake, do help to control intake and thus, can be effective dietary tool for overweight individuals.

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APPENDICES

APPENDIX A

TABLES AND FIGURES

Table 1. Depiction of study design – complete 2x2x2 between-subjects factorial design.

	Normal Weight		Overweight	
	Unrestrained	Restrained	Unrestrained	Restrained
Single-Serving Package Unit Size	n = 8	n = 8	n = 8	n = 8
Standard Package Unit Size	n = 8	n = 8	n = 8	n = 8

Table 2. Baseline characteristics of participants ($M \pm SD$).

	Normal Weight				Overweight			
	Unrestrained, SS Package <i>n</i> =8	Unrestrained, ST Package <i>n</i> =8	Restrained, SS Package <i>n</i> =8	Restrained, ST Package <i>n</i> =8	Unrestrained, SS Package <i>n</i> =8	Unrestrained, ST Package <i>n</i> =8	Restrained, SS Package <i>n</i> =8	Restrained, ST Package <i>n</i> =8
Age (years) ^{1,2}	22.0 $\pm$ 2.1	21.1 $\pm$ 1.6	24.4 $\pm$ 1.9	24.0 $\pm$ 2.4	23.8 $\pm$ 4.2	24.4 $\pm$ 3.5	24.5 $\pm$ 4.3	25.6 $\pm$ 4.0
Gender (%) ³								
Male	75.0	62.5	12.5	25.0	62.5	100.0	37.5	50.0
Female	25.0	37.5	87.5	75.0	37.5	0.0	62.5	50.0
BMI (kg/m ²) ¹	22.2 $\pm$ 1.0	22.0 $\pm$ 1.9	22.4 $\pm$ 1.2	22.2 $\pm$ 1.5	31.2 $\pm$ 4.7	29.6 $\pm$ 2.5	28.0 $\pm$ 3.6	30.4 $\pm$ 5.1
Restraint Score ^{2,4}	8.1 $\pm$ 2.7	5.0 $\pm$ 3.2	14.9 $\pm$ 1.8	15.1 $\pm$ 1.4	6.8 $\pm$ 4.3	8.9 $\pm$ 1.8	16.4 $\pm$ 2.5	15.3 $\pm$ 2.1
Race (%)								
White	50.0	87.5	100.0	100.0	87.5	87.5	62.5	75.0
Other	50.0	12.5	0.0	0.0	12.5	12.5	37.5	25.0
Non-Hispanic/Latino (%)	87.5	100.0	100.0	100.0	87.5	100.0	100.0	100.0
Education Level (%)								
High School (10-12 years)	0.0	0.0	0.0	12.5	0.0	0.0	0.0	0.0
Some College	75.0	75.0	0.0	25.0	50.0	50.0	25.0	37.5
College or University Degree	25.0	12.5	62.5	37.5	25.0	37.5	50.0	37.5
Graduate or Professional Education	0.0	12.5	37.5	25.0	25.0	12.5	25.0	25.0

Table 2. Continued.

	Normal Weight				Overweight			
	Unrestrained, SS Package <i>n</i> =8	Unrestrained, ST Package <i>n</i> =8	Restrained, SS Package <i>n</i> =8	Restrained, ST Package <i>n</i> =8	Unrestrained, SS Package <i>n</i> =8	Unrestrained, ST Package <i>n</i> =8	Restrained, SS Package <i>n</i> =8	Restrained, ST Package <i>n</i> =8
Marital Status (%)								
Married	25.0	0.0	25.0	25.0	25.0	25.0	12.5	50.0
Divorced	0.0	0.0	0.0	12.5	0.0	0.0	0.0	0.0
Never Married	75.0	87.5	75.0	62.5	62.5	62.5	87.5	50.0
Not Married (Living with Significant Other)	0.0	12.5	0.0	0.0	12.5	12.5	0.0	0.0
First Session Hedonic Ratings of Pretzels (mm) ⁵	68.1 ± 10.2	62.9 ± 8.4	65.1 ± 10.7	70.0 ± 10.1	72.8 ± 11.1	64.4 ± 12.6	62.8 ± 11.7	67.5 ± 9.1

Note: SS Package = single-serving package unit size condition; ST Package = standard package unit size condition; BMI = body mass index. ¹Main effect of Weight Status;

²Main effect of Restraint Status; ³Significant Difference between Normal Weight, Restrained, SS Package and Overweight, Unrestrained, ST Package; ⁴Interaction of Weight

Status x Package Unit Size x Restraint Status (normal weight individuals randomized to ST package had significantly lower restraint scores than overweight individuals

randomized to ST package); ⁵Interaction of Package Unit Size x Restraint Status (unrestrained eaters randomized to SS package had a significantly higher degree of liking for pretzels than unrestrained eaters randomized to ST package).

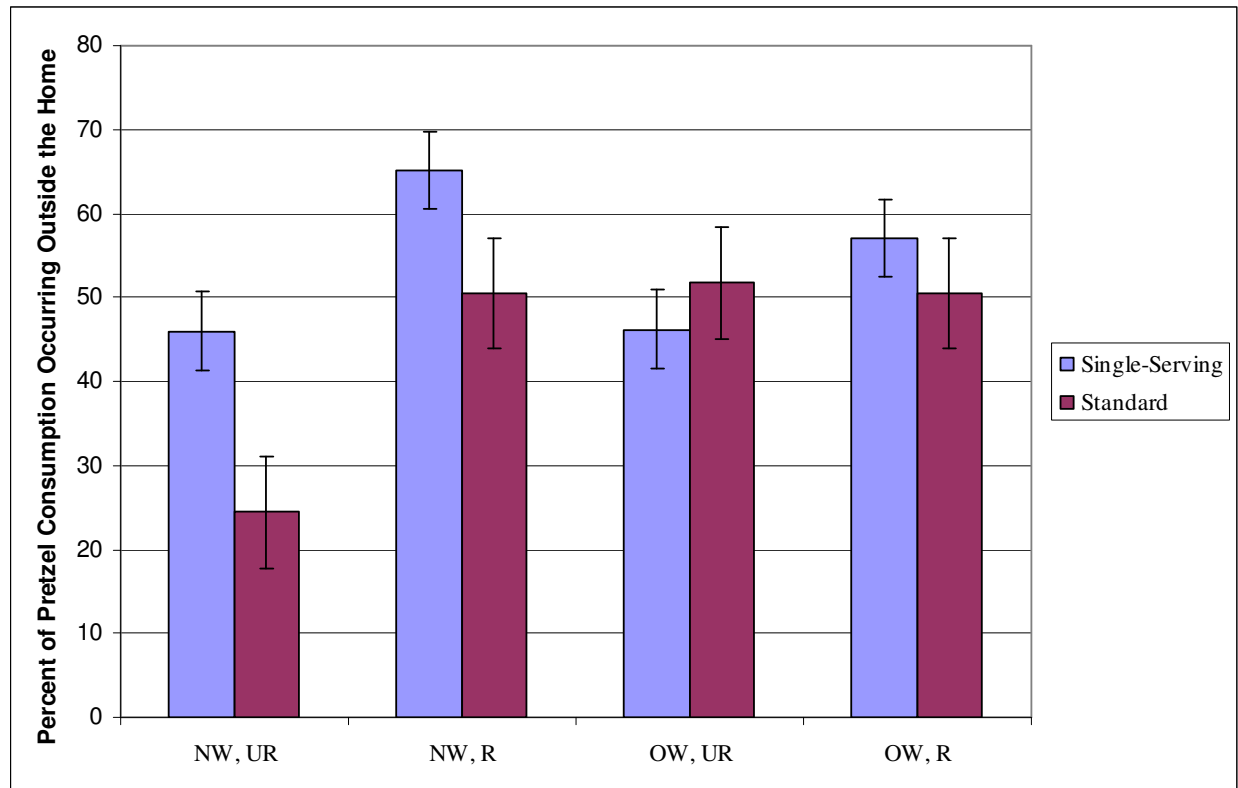


Figure 1. Percent of pretzel consumption occurring outside the home over a 4-day period in all eight groups. No significant interactions or main effects were found. Percentage of times pretzels were consumed away from home was similar across all groups. Data are mean $\pm$ standard error. NW = normal weight; OW = overweight; UR = unrestrained; R = restrained.

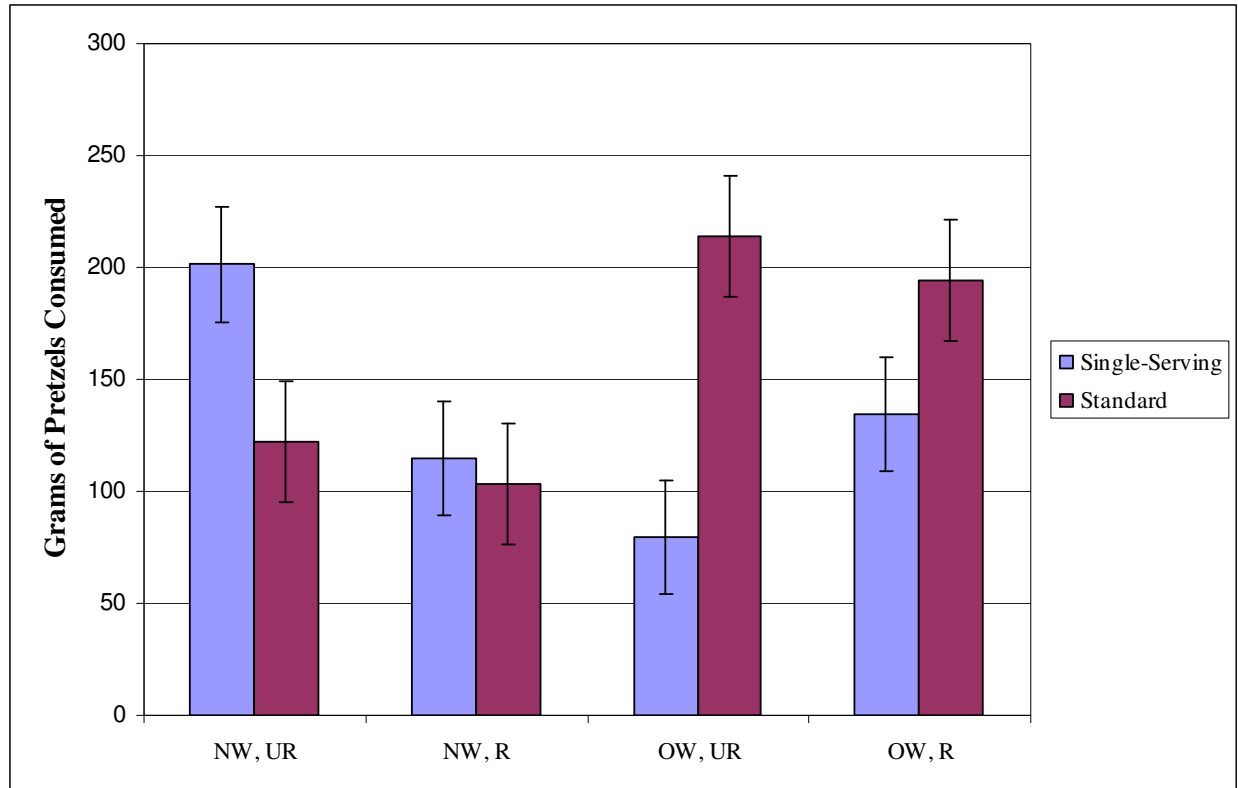


Figure 2. Total grams of pretzels consumed over a 4-day period in all eight groups. No combined effect of weight status and dietary restraint status on the relationship between package unit size and food intake was observed. Data are mean $\pm$ standard error. NW = normal weight; OW = overweight; UR = unrestrained; R = restrained.

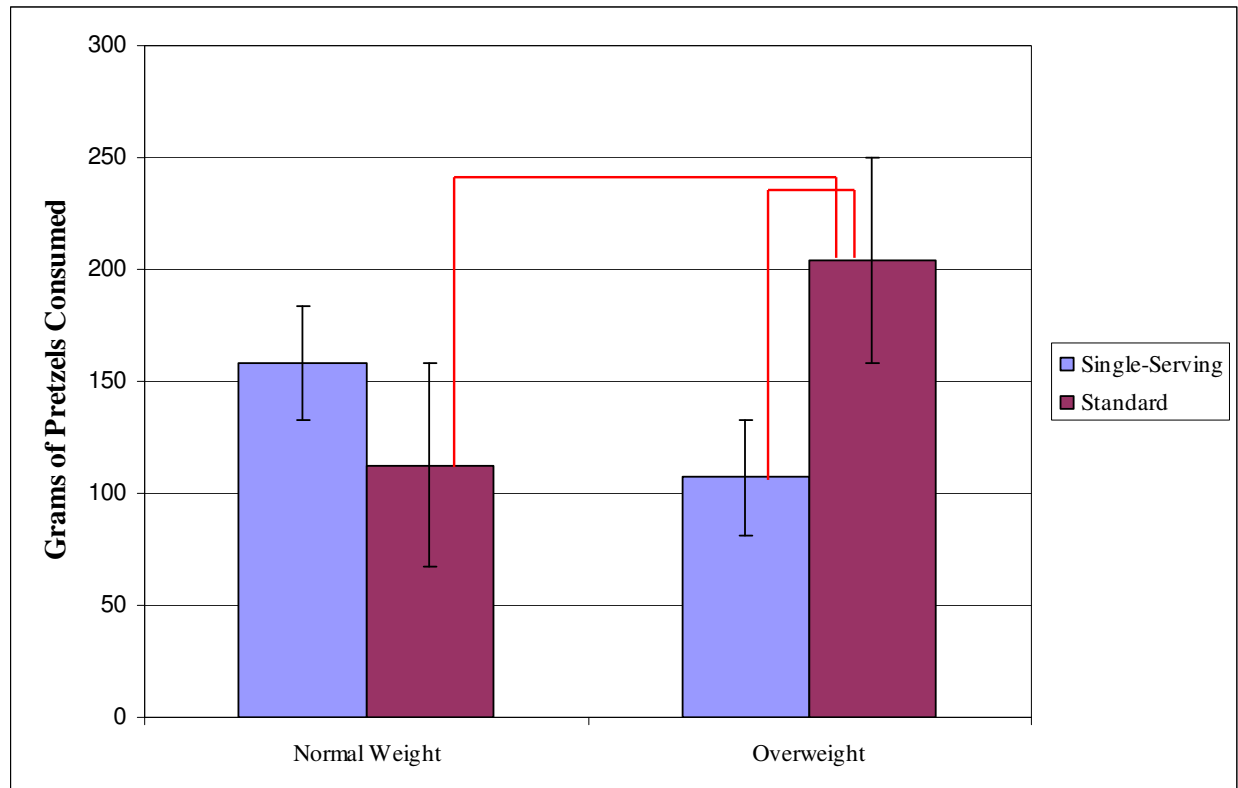


Figure 3. Total grams of pretzels consumed over a 4-day period in normal weight and overweight participants. A 3-factor ANOVA showed a significant ($p = 0.01$) interaction between weight status and package unit size, such that overweight participants ate significantly more grams of pretzels from standard size packages than from single-serving packages, and overweight participants ate significantly more than normal weight participants in the standard size condition. Data are mean $\pm$ standard error. Bars with connecting red lines are statistically different ($p < 0.05$).

APPENDIX B

FLYERS, FORMS, AND QUESTIONNAIRES

IRB: FORM B APPLICATION

All applicants are encouraged to read the Form B guidelines. If you have any questions as you develop your Form B, contact your Departmental Review Committee (DRC) or Research Compliance Services at the Office of Research.

FORM B

IRB # _____

Date Received in OR _____

THE UNIVERSITY OF TENNESSEE

Application for Review of Research Involving Human Subjects

I. IDENTIFICATION OF PROJECT

1. Principal Investigator(s):

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2. Project Classification: Thesis

3. **Title of Project:** Do Weight Status and the Level of Dietary Restraint Moderate the Relationship between Package Unit Size and Food Intake?
4. **Starting Date:** 6/7/2011
5. **Estimated Completion Date:** 11/1/2012
6. **External Funding:** N/A

II. PROJECT OBJECTIVES

The estimated prevalence of obesity among adults in 2007-2008 was 33.8% and the combined estimated prevalence of overweight and obesity was 68.0%.¹ Although there are no clear reasons for the current obesity epidemic, there is a general consensus that environmental dietary factors, such as package unit size, encourage excessive food intake and positive energy balance.^{2,3} It is believed that the package unit size of food indirectly influences food intake by impacting the accuracy of consumption monitoring.^{3,4} Large packages decrease the accuracy of consumption monitoring by making it difficult to assess how many servings have been consumed in one sitting, while small single-serving packages can increase the accuracy of consumption monitoring by providing a clear definition of what a standard serving is and how much one has consumed.³⁻⁵ Therefore, it has been proposed that small, single-serving packages of snack foods may help reduce energy intake.^{4,5} To date, limited studies have been conducted in this area and the results are inconsistent.⁴⁻⁹ Mixed results could be related to differences in participant variables, specifically weight status and level of dietary restraint (a term that refers to the amount of control exerted over food intake).^{4,9} These individual characteristics may interact with food package unit size to influence one's food intake.^{3,4} Overweight individuals or restrained eaters may more closely monitor the volume of food they consume as compared to normal weight or unrestrained eaters.^{4,9} The [smaller] size of food packaging may aid in monitoring food consumption and thus, influence how much food is consumed in overweight and/or restrained eaters.^{3,4} **Therefore, the objective of this study is to determine if weight status and the level of dietary restraint moderate the relationship between package unit size and food intake.**

Specific Aims:

1. Determine the effect of dietary restraint on the relationship between package unit size and food intake.
2. Determine the effect of weight status on the relationship between package unit size and food intake.
3. Determine the combined effect of weight status and dietary restraint on the relationship between package unit size and food intake.

To address all three specific aims: Two groups of overweight, restrained participants, two groups of normal weight, restrained participants, two groups of overweight, unrestrained participants, and two groups of normal weight, unrestrained participants will be randomly assigned to receive either a box of single-serving pretzel packages or a box of standard pretzel packages for four days. Total grams of pretzels consumed will be determined by subtracting pre- and post-consumption weight of snack packages provided. Comparisons will then be made between groups.

Impact: *The underlying assumption of the use of single-serving packages is that they will help individuals eat less. Thus, it is important to assess the efficacy of this packaging in controlling or reducing energy intake. This study's results can help nutrition professionals determine if this is a useful tool to assist with food intake control/reduction and if so, to which individuals this dietary tool can best be applied.*

III. DESCRIPTION AND SOURCE OF RESEARCH PARTICIPANTS

Recruitment

Sixty-four males and females will participate in this study. Participants will be recruited from The University of Tennessee-Knoxville and the surrounding Knoxville area. Flyers describing the study will be posted around campus and e-mails with an attached flyer will be sent out to University of Tennessee-Knoxville academic department list-servs. Additionally, flyers will be posted in local health clubs, fitness centers, and parks. This study will recruit participants using a rolling enrollment strategy. Interested individuals will be asked to contact the Healthy Eating and Activity Laboratory (HEAL) for an initial phone screening to determine eligibility prior to study enrollment.

Eligibility Criteria

Eligibility for this study will be based upon the following criteria:

- 9) Male and females aged 18-35 years old.
- 10) Body Mass Index (BMI) between 18.5-24.9 kg/m² or BMI between 25-39.9 kg/m².
 - a. For normal weight groups: BMI of 18.5-24.9 kg/m².
 - b. For overweight groups: BMI of 25-39.9 kg/m².
- 11) Dietary restraint scores of either ≤ 12 or > 12 on the Three Factor Eating Questionnaire-Cognitive Restraint scale (TFEQ-R).¹⁰
 - a. For unrestrained groups: ≤ 12 .
 - b. For restrained groups: > 12 .
- 12) Do not have unfavorable preference toward pretzels.
- 13) Do not have allergies to pretzel ingredients.
- 14) Do not have a health condition or use medication that affects eating or requires a therapeutic diet.
- 15) Must have a consistent schedule during the time of the study.
- 16) Must agree to instructions to not share pretzel snack packages with others.

Participants will be excluded from the study based upon the following criteria:

- 7) BMI below 18.5 or above 39.9 kg/m².
- 8) Have an unfavorable preference toward pretzels.
- 9) Have allergies to pretzel ingredients (wheat flour).
 - a. Severe allergies to nuts – Snyder's® of Hanover pretzels are made in a facility that handles peanut butter.
- 10) Are unwilling to consume pretzels during the time of the study.
- 11) Are pregnant or breastfeeding.
- 12) Do not meet one or more of the other above mentioned eligibility requirements.

Compensation

Upon completing the food study and attending the second session, participants will be compensated \$10.00 (gift card) for their efforts and involvement in this study. Successful completion of the food study will be defined as the return of 100% of the pretzel snack packages provided, as well as the completion of the self-report of pretzel consumption form. Participants will also need to attend both in-lab sessions.

IV. METHODS AND PROCEDURES

Study Design

In order to determine if weight status and the level of dietary restraint moderate the relationship between package unit size and food intake, this study will examine the independent effects of the level of dietary restraint and weight status on the relationship between package unit size and food intake, as well as the combined effects of these two variables on the above mentioned relationship. Thus, in order to address Specific Aim 1, the effect of dietary restraint (unrestrained versus restrained participants) on the relationship between package unit size and food intake will be examined. To address Specific Aim 2, the effect of weight status (normal weight versus overweight participants) on the relationship between package unit size and food intake will be examined, and to address Specific Aim 3, the combined effects of dietary restraint and weight status on the relationship between package unit size and food intake will be examined. A complete 2x2x2 between-subjects factorial design will be used in this study. Using this

design, two groups of overweight, restrained participants, two groups of normal weight, restrained participants, two groups of overweight, unrestrained participants, and two groups of normal weight, unrestrained participants will be randomly assigned to receive either a box of single-serving pretzel packages or a box of standard pretzel packages for four days. Thus, the between-subject factors are dietary restraint (unrestrained versus restrained), weight status (normal weight versus overweight), and package unit size (single-serving versus standard). This study will be quasi-experimental in that participants will be non-randomly assigned to groups based on weight and dietary restraint status. However, for the between-subject factor of package unit size, participants will be randomly assigned to receive either the single-serving package condition or the standard size package condition. Total grams of the provided food (pretzels) consumed will be the primary dependent variable and will be calculated by subtracting pre- and post-consumption weight of snack packages provided.

Procedure

Following completion of the initial phone screen, eligible participants will be scheduled for a 30-minute individual session on Thursdays or Fridays at the HEAL Lab. During this initial session, informed consent will be obtained, height and weight will be measured, and participants will rate their liking of pretzels on a 100-mm Visual Analog Scale (VAS). To continue participation in the study, participants will have to have a BMI greater than 18.5 kg/m² (but below 39.9 kg/m²), will have to indicate a favorable preference for pretzels (scoring > 50 mm on the VAS), and will have to indicate that they will be willing to eat the pretzels during the study period. Participants will be grouped based on dietary restraint classification (unrestrained eater versus restrained eater), which was measured during the initial phone screen, and weight status classification (normal weight versus overweight). Based upon these groupings (four in all), participants will be randomly assigned to either the single-serving package unit size condition or the standard package unit size condition, giving a total of eight groups.

At this initial session, participants will also be given either a box of single-serving pretzel packages or a box of standard size pretzel packages corresponding to their randomly assigned package unit size condition. Participants will be informed that they are to take home the box of pretzels for a period of four days and then return the box of pretzel packages to the HEAL Lab at a second session. For participants who attend the initial session on Thursday, this means they will return the box of pretzels to the HEAL Lab on Monday, and for those attending on Friday, they will return the box of pretzels to the HEAL Lab on Tuesday. Participants will be instructed to bring back all snack packages of pretzels, including packages that have been opened or emptied. Participants will be informed that during this 4-day period, they will need to refrain from sharing the provided pretzels with others and will need to at least taste the pretzels, but can eat as little or as much as they desire. In addition, participants will be given a brief form to fill out during the study period documenting when (date/time) and where they consumed the provided pretzels. Prior to leaving, participants will be reminded of the date and time of their second 10-minute session that they must attend four days from the initial session (either Monday or Tuesday depending on starting day).

At the second session, participants will bring back all pretzel packages, including packages that have been opened or emptied. In addition, participants will bring back the completed form documenting when (date/time) and where they consumed the provided pretzels. Participants will be asked if anyone other than themselves had consumed the provided pretzels over the 4-day study period. In order to fulfill the original purpose of the study as it will be presented to participants (the participants will be told that they are being recruited for a study regarding the effects of recent snack food consumption on liking of snack foods), participants will once again be asked to rate their liking of pretzels on a 100-mm VAS. Following this last measurement, participants will be debriefed, compensated (\$10 gift card), and thanked for their participation.

Pretzel Package Unit Size

Pretzel packages will be provided in either a single-serving package unit size (0.9 oz.) or a standard package unit size (10.0 oz.). Participants will receive one box of either the single-serving Snyder's® of Hanover pretzel packages or the standard Snyder's® of Hanover pretzel packages corresponding to their randomly assigned package unit size condition. Pretzels will be provided to participants in the food manufacturer's original packaging. To keep amount of food provided consistent (so that only package unit size is manipulated), boxes containing the single-serving size packages will

have twenty-two, 0.9-oz. packages of pretzels, and boxes containing the standard size packages will have two, 10-oz. packages of pretzels.

Measures

Basic demographic information (age, sex, education, marital status, race, and ethnicity) will be assessed at entry into the study.

Anthropometrics

Participant height and weight will be gathered via self-report during the initial phone screening. Participant height and weight will also be assessed during the first session using a portable stadiometer and an electric scale, respectively. Measurements will be made according to standard procedures.¹¹ Height will be recorded to the nearest one-eighth inch and weight will be recorded to the nearest one-tenth pound. BMI will be calculated by dividing the weight in kilograms by height in meters squared. If participant BMI is below 18.5 or above 39.9 kg/m², they will be excluded from the study.

Dietary Restraint

During the initial phone screening, the level of dietary restraint will be determined using the TFEQ-R.¹⁰ This tool is a part of the TFEQ, which has proven validity and reliability in measuring three dimensions of eating behavior: dietary restraint, disinhibition, and hunger.¹⁰ The TFEQ-R, a 21-item assessment tool, measures dietary restraint on a scale of 0-21, with 0 being a completely unrestrained eater and 21 being a completely restrained eater.¹⁰ A maximum of one point is awarded per item. Items include true/false statements, as well as close-ended questions. Participants scoring ≤ 12 will be classified as an unrestrained eater, while participants scoring > 12 will be classified as a restrained eater.

Liking of Pretzels

Participants will rate their degree of liking of pretzels both at the first and second session using a 100-mm VAS. This scale will use the anchors of “extremely dislike” on the left and “extremely like” on the right. Scores ≤ 50 mm on the VAS at the initial session will result in participant exclusion from the study.

Self-Report of Pretzel Consumption

At the first session, participants in both groups will be given a brief form to fill out during the 4-day study period, documenting when (date/time) and where they consumed the provided pretzels. Participants will return the completed form at the second session. This will be done to assess whether pretzel consumption from single-serving packages is related to a convenience factor. For example, if pretzel consumption is related to a convenience factor, then individuals may be consuming pretzels from small, single-serving packages because they are easily transported from one place to another (as compared to standard size packages). If, therefore, participants are consuming more pretzels outside of the home, it might indicate they are doing so out of convenience. Thus, in order to accurately interpret study results as related to the original design of this study, it will be important to detect that participants are not eating more from these single-serving packages due to this added level of convenience.

Measured Pretzel Consumption

Pretzels provided to participants in each condition will be measured in the Snyder's® of Hanover original packaging on an electronic food scale (Denver Instrument Co., Arvada, CO) before giving them to participants to take home for four days. At the second session, all pretzel packages, including those that have been opened or emptied, will once again be measured using the same electronic scale. Total grams of pretzels consumed will be determined by subtracting pre- and post-consumption weight of snack packages provided.

Statistical Analyses

A 2x2x2 ANOVA (unrestrained/restrained x normal weight/overweight x single-serving package/standard size package) and a Chi-square test will be performed to analyze differences between the groups in baseline characteristics relevant to the investigation, such as age, hedonic ratings of pretzels, gender, and race/ethnicity. To analyze differences between the groups on the primary outcome measure of total grams of pretzels consumed, a 2x2x2 ANOVA will also be performed, using significant differences ($p < 0.05$) in baseline characteristics as covariates. Post hoc pairwise comparisons with Bonferroni adjustments will be made for significant outcomes ($p < 0.05$) to determine exactly which groups differed in total grams of pretzels consumed. All statistical analyses will be performed using SPSS Statistics 18.0¹², with significance level set at 0.05. Results from

these analyses will be used to assess 1) if the level of dietary restraint interacted with package unit size to influence food intake, 2) if weight status interacted with package unit size to influence food intake, and/or 3) if the level of dietary restraint and weight status interacted with package unit size to influence food intake.

V. SPECIFIC RISKS AND PROTECTION MEASURES

Risks

The risks of participating in this study are small. If participants are allergic to the pretzels given to them to take home during the study period, they may have an allergic reaction. However, the pretzels used in this study are a common snack food, and all participants will be asked about food allergies during the initial eligibility screening process.

Adverse Events and External Review for Data Safety

Adverse events reported during the course of the study will be documented by the investigator in charge and reported to the University of Tennessee's Institutional Review Board.

Confidentiality

The information in the study records will be kept confidential. Participants will be given a unique identification number that will be used on all documents with no references to individual names, addresses, or phone numbers. Data will be stored securely in locked filing cabinets and in password-protected electronic files in Room 102 in the Jessie Harris Building. Data will be made available only to persons conducting the study, unless participants specifically give permission in writing to do otherwise. No reference will be made in oral or written reports which could link participants to the study.

VI. BENEFITS

Participants will receive no benefits from participation in this research study.

VII. METHODS FOR OBTAINING "INFORMED CONSENT" FROM PARTICIPANTS

The study will be described to interested individuals individually via telephone and then in more detail at a face-to-face initial session at the University of Tennessee. Interested participants will be told that the purpose of the study is to investigate the effects of recent snack food consumption on liking of snack foods. After prospective participants interested in the study have completed an initial phone screening, those who are deemed eligible will be given more information about the study and asked if they are still interested in participating. If still interested, participants will be asked to come to the HEAL Lab for an initial session to sign a consent form approved by the University of Tennessee Institutional Review Board and to receive further instructions regarding the study. Signed consent forms will be stored in locked file cabinets in the HEAL Lab.

VIII. QUALIFICATIONS OF THE INVESTIGATOR(S) TO CONDUCT RESEARCH

Chrystal Haire, the Co-Principal Investigator, is a graduate student at the University of Tennessee-Knoxville, pursuing a dual Master of Science in Public Health Nutrition and Master of Public Health degree. She has worked in the HEAL Lab for the past year and has had experience working on two behavioral weight loss interventions with Dr. Hollie Raynor, a clinical psychologist and dietitian. Dr. Raynor has been a Principal Investigator and Co-Investigator on several studies funded by the National Institutes of Health (NIH) examining behavioral treatment approaches to weight loss and weight loss maintenance. Dr. Raynor will serve as both a Co-Principal Investigator and faculty advisor on this study and will provide direction and guidance as needed.

IX. FACILITIES AND EQUIPMENT TO BE USED IN THE RESEARCH

Research space in the Jessie Harris Building will be used for this investigation. The space is in Room 102, is 768 square feet, and includes a group meeting room, two offices, a reception area, a storage closet, and a kitchen. Height and weight measurements will take place behind closed doors (using the above described methods) to protect individual privacy. Sessions will take place in the group meeting room. Data will be stored in locked filing cabinets and in password-protected files in the HEAL Lab (Room 102) in the Jessie Harris Building. Data will be analyzed using SPSS Statistics 18.0.¹²

References

1. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among U.S. adults, 1999-2008. *J Am Med Assoc.* 2010;303(3):235-41.
2. French SA, Story M, Jeffery RW. Environmental influences on eating and physical activity. *Annu Rev Public Health.* 2001;22:309-35.
3. Wansink B. Environmental factors that increase the food intake and consumption volume of unknowing consumers. *Annu Rev Nutr.* 2004;24:455-79.
4. Raynor HA, Wing RR. Package unit size and amount of food: Do both influence intake? *Obesity.* 2007;15(9):2311-19.
5. Stroebele N, Ogden LG, Hill JO. Do calorie-controlled portion sizes of snacks reduce energy intake? *Appetite.* 2009;52(3):793-6.
6. Devitt AA, Mattes RD. Effects of food unit size and energy density on intake in humans. *Appetite.* 2004;42(2):213-20.
7. Raynor HA, Van Walleghen EL, Niemeier H, Butryn ML, Wing RR. Do food provisions packaged in single-servings reduce energy intake at breakfast during a brief behavioral weight-loss intervention? *J Am Diet Assoc.* 2009;109(11):1922-25.
8. Freedman MR, Brochado C. Reducing portion size reduces food intake and plate waste. *Obesity.* 2010;18(9):1864-6.
9. Wansink B, Payne CR, Shimizu M. The 100-calorie semi-solution: Sub-packaging most reduces intake among the heaviest. *Obesity.* 2011.
10. AJ Stunkard, Messick S. The three-factor eating questionnaire to measure dietary restraint, disinhibition and hunger. *J Psychosom Res.* 1985;29(1):71-83.
11. Lohman TR, Roche AF, Martorell R. *Anthropometric Standardization Reference Manual.* Champaign, IL: Human Kinetics; 1988.
12. SPSS, Inc. *SPSS for Windows.* Release 18.0. Chicago, IL: SPSS, Inc.; 2010.

X. RESPONSIBILITY OF THE PRINCIPAL/CO-PRINCIPAL INVESTIGATOR(S)

The following information must be entered verbatim into this section:

By compliance with the policies established by the Institutional Review Board of The University of Tennessee the principal investigator(s) subscribe to the principles stated in "The Belmont Report" and standards of professional ethics in all research, development, and related activities involving human subjects under the auspices of The University of Tennessee. The principal investigator(s) further agree that:

- 1. Approval will be obtained from the Institutional Review Board prior to instituting any change in this research project.**
- 2. Development of any unexpected risks will be immediately reported to Research Compliance Services.**
- 3. An annual review and progress report (Form R) will be completed and submitted when requested by the Institutional Review Board.**
- 4. Signed informed consent documents will be kept for the duration of the project and for at least three years thereafter at a location approved by the Institutional Review Board.**

XI. SIGNATURES

ALL SIGNATURES MUST BE ORIGINAL. The Principal Investigator should keep the original copy of the Form B and submit a copy with original signatures for review. Type the name of each individual above the appropriate signature line. Add signature lines for all Co-Principal Investigators, collaborating and student investigators, faculty advisor(s), department head of the Principal Investigator, and the Chair of the Departmental Review Committee. The following information should be typed verbatim, with added categories where needed:

Principal Investigator: Dr. Hollie Raynor

Signature: _____ **Date:** _____

Co-Principal Investigator: Chrystal Haire

Signature: _____ **Date:** _____

Student Advisor (if any): Dr. Hollie Raynor

Signature: _____ **Date:** _____

XII. DEPARTMENT REVIEW AND APPROVAL

The application described above has been reviewed by the IRB departmental review committee and has been approved. The DRC further recommends that this application be reviewed as:

[x] Expedited Review -- Category(s): _____**4**_____

OR

[] Full IRB Review

Chair, DRC: _____**Dr. Michael Zemel**_____

Signature: _____ **Date:** _____

Department Head: _____**Dr. Jay Whelan**_____

Signature: _____ **Date:** _____

Protocol sent to Research Compliance Services for final approval on (Date) : _____

Approved:
Research Compliance Services
Office of Research
1534 White Avenue

Signature: _____ **Date:** _____

For additional information on Form B, contact the Office of Research Compliance Officer or by phone at (865) 974-3466.

Snack Food Impact Study

Interested in participating in a brief study that gives you FREE snack food and \$10 compensation?

Free Snacks

\$10



Eligibility requirements:

- Between 18 and 35 years-old
- Willing to eat pretzels
- Like pretzels



Excluded individuals:

- Those with allergies to wheat flour or nuts
- Individuals who are pregnant or breastfeeding



If interested, please contact Chrystal at the Healthy Eating and Activity Laboratory at 974-0754.

Healthy Eating & Activity Lab
Snack Food Impact Study
974-0754

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Are You a Healthy Snacker?

Snack Food Impact Study

Interested in participating in a brief study that gives you FREE snack food and \$10 compensation?

Free Snacks

\$10



Eligibility requirements:

- Between 18 and 35 years-old
- Willing to eat pretzels
- Like pretzels



Excluded individuals:

- Those with allergies to wheat flour or nuts
- Individuals who are pregnant or breastfeeding



If interested, please contact Chrystal at the Healthy Eating and Activity Laboratory at 974-0754.

Healthy Eating & Activity Lab Snack Food Impact Study 974-0754	Healthy Eating & Activity Lab Snack Food Impact Study 974-0754	Healthy Eating & Activity Lab Snack Food Impact Study 974-0754	Healthy Eating & Activity Lab Snack Food Impact Study 974-0754	Healthy Eating & Activity Lab Snack Food Impact Study 974-0754	Healthy Eating & Activity Lab Snack Food Impact Study 974-0754	Healthy Eating & Activity Lab Snack Food Impact Study 974-0754
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Do you like to snack?

Snack Food Impact Study

Interested in participating in a brief study that gives you a box of FREE snack food and \$10 compensation?

Free Snacks



\$10

Eligibility requirements:

- Between 18 and 35 years-old
- Willing to eat pretzels
- Like pretzels



Excluded individuals:

- Those with allergies to wheat flour or nuts
- Individuals who are pregnant or breastfeeding



If interested, please contact Chrystal at the Healthy Eating and Activity Laboratory at 974-0754.

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Recruitment Flyer 5

Do you like to eat healthy snacks?

Snack Food Impact Study

Interested in participating in a brief study that gives you a box of FREE snack food and \$10 compensation?

Free Snacks



\$10

Eligibility requirements:

- Between 18 and 35 years-old
- Willing to eat pretzels
- Like pretzels



Excluded individuals:

- Those with allergies to wheat flour or nuts
- Individuals who are pregnant or breastfeeding



If interested, please contact Chrystal at the Healthy Eating and Activity Laboratory at 974-0754.

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Snack Food Impact Study Phone Script

Hello, this is _____. Thanks for calling about the Snack Food Impact (SFI) Study. Let me first tell you about the study, so that you can decide if you are interested in participating. The purpose of the study is to investigate the effect of recent snack food consumption on liking of snack foods. This study will require two brief in-lab sessions here at the HEAL Lab on the University of Tennessee campus. Participants in this study will be scheduled for an initial 30-minute appointment in our lab on either Thursday or Friday. During this session, informed consent will be obtained and height and weight measures will be taken. Participants will then be given a form asking them to rate their liking of a particular snack food. In addition, they will be given a box of this snack food, pretzels, to take home for a period of four days. During this 4-day period, participants will need to refrain from sharing the provided pretzels with others. Participants will also need to at least taste the pretzels, but can eat as little or as much as they desire. Additionally, participants will be given a brief form to fill out during this time period documenting when (date/time) and where they consumed the pretzels. Prior to leaving, participants will be reminded of the date and time of their second 10-minute session that they must attend four days from the initial session (which will either be on a Monday or Tuesday depending on which day they come in for their initial session).

At the second session, participants will bring back all pretzel packages, including packages that have been opened or emptied. In addition, participants will bring back the completed form documenting when (date/time) and where they consumed the provided pretzels. To determine the effect of recent snack food consumption on their liking of the snack food provided, participants will once again be asked to rate their liking of the provided pretzels. Upon completion of the study requirements, including the two brief in-lab sessions, participants will receive a \$10 gift card. If you are interested in participating in this study, I have some questions to ask you to determine your initial eligibility. This will take about 10 minutes.

GO TO SCREENING FORM.

SFI STUDY SCREENING FORM

Office Use Only

PID #: _____

Date: _____

1) Gender: ☐ F ☐ M

2) a) Age: _____

b) Date of birth: ____/____/____ (must be
between 18 and 35)

If age is not between 18 and 35: I am sorry, but the age range we're recruiting for is 18-35. Since you are ____ yrs old, you are not eligible for this study. Thank you very much for your time.

3) a) Which of the following best describes your racial heritage? (you may choose more than one)

- ☐ American Indian or Alaskan Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or other Pacific islander
☐ White
☐ Other _____

b) Which of the following best describes your ethnic heritage?

- ☐ Hispanic or Latino
☐ Not Hispanic or Latino

4) a) Current weight: _____ pounds b) Height: ____ feet ____ inches

c) Current BMI: _____ (must be between 18.5 and 39.9) BMI = kg/m^2 or $(\text{lbs/in}^2) \times 703$

If BMI is below 18.5 or above 39.9: I'm sorry, but because your height and weight are not within the range for this study, you aren't eligible. Thank you very much for your time.

5) Please rate your liking of pretzels using a scale of 1-5, with 1 meaning do not like and 5 meaning like very much.

Pretzels				
1	2	3	4	5

If pretzels is rated less than 3: I'm sorry, but since you do not like pretzels, you are ineligible for the study. Thank you for your interest.

6) Are you willing to at least taste the provided pretzels during the 4-day period that you will be required to take the snack food home with you?

- ☐ Yes ☐ No (**INELIGIBLE** if unwilling to taste pretzels)

If NO to Q6: I am sorry, but because participation in this study requires that you at least taste the provided pretzels during the 4-day study period, you are not eligible. Thank you for your time.

- 7) Are you willing to agree to not share the provided box of pretzel packages with others?
☐ Yes ☐ No **(INELIGIBLE)**

If NO to Q7: I am sorry, but because you are not willing to abide by the instructions to not share the box of pretzel packages with others, you are not eligible for this study. Thank you for your time.

Now I have some health-related questions.

- 8) **Ask only of females:** Are you currently pregnant or breastfeeding?
☐ No ☐ Yes **(INELIGIBLE)**

If YES to Q8: I am sorry, but due to the fact that you are currently pregnant/breastfeeding you are not eligible for this study. Thank you very much for your time.

- 9) Do you have any food allergies or dietary restrictions?
☐ No ☐ Yes → Explain _____
(INELIGIBLE if wheat flour or nuts)

If YES to Q9: I am sorry, but due to the fact that you are allergic to _____, you are not eligible for this study because the snack food contains _____. Thank you for your time.

- 10) Do you have a health condition that influences eating or requires a therapeutic diet?
☐ No ☐ Yes **(INELIGIBLE)**

- 11) Are you currently taking medications that influence eating?
☐ No ☐ Yes **(INELIGIBLE)**

If YES to Q10-11: I am sorry, but due to the fact that you have a health condition that influences eating/take _____ medication, you are not eligible for this study. Thank you for your time.

12-A) Please answer true or false to the following statements. **(Give bolded answer 1 point.)**

Points

1) When I have eaten my quota of calories, I am usually good about not eating any more.	T	F	
2) I deliberately take small helpings as a means of controlling my weight.	T	F	
3) Life is too short to worry about dieting.	T	F	
4) I have a pretty good idea of the number of calories in common food.	T	F	
5) While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it.	T	F	
6) I enjoy eating too much to spoil it by counting calories or watching my weight.	T	F	
7) I often stop eating when I am not really full as a conscious mean of limiting the amount that I eat.	T	F	
8) I consciously hold back at meals in order not to gain weight	T	F	
9) I eat anything I want, any time I want.	T	F	
10) I count calories as a conscious means of controlling my weight.	T	F	
11) I do not eat some foods because they make me fat.	T	F	
12) I pay a great deal of attention to changes in my figure.	T	F	
Total Points			

12-B) Please answer the following questions with one of the responses that is appropriate for you.

(Give **bolded** answer 1 point.)

Points

1) How often are you dieting in a conscious effort to control your weight? Rarely Sometimes Usually Always	
2) Would a weight fluctuation of 5 lbs affect the way you live your life? Not at all Slightly Moderately Very Much	
3) Do your feelings of guilt about overeating help you to control your food intake? Never Rarely Often Always	
4) How conscious are you of what you are eating? Not at all Slightly Moderately Extremely	
5) How frequently do you avoid “stocking up” on tempting foods? Almost never Seldom Usually Almost always	
6) How likely are you to shop for low calorie foods? Unlikely Slightly unlikely Moderately likely Very likely	
7) How likely are you to consciously eat slowly in order to cut down on how much you eat? Unlikely Slightly likely Moderately likely Very likely	
8) How likely are you to consciously eat less than you want? Unlikely Slightly likely Moderately likely Very likely	
9) On a scale from 0-5, where 0 means no restraint in eating (eating whatever you want, whenever you want) and 5 means total restraint (constantly limiting food intake and never “giving in”), what number would you give yourself? 0 – eat whatever you want, whenever you want 1 – usually eat whatever you want, whenever you want 2 – often eat whatever you want, whenever you want 3 – often limit food intake, but often “give in” 4 – usually limit food intake, rarely “give in” 5 – constantly limiting foods intake, never “giving in”	
Total Points	

Total Points (13-A + 13-B):

If Total Points (12-A + 12-B) = $\leq$ 12 and have BMI between 18.5-24.9 kg/m² – Place in Group A. If Total Points (12-A + 12-B) = $>$ 12 and have BMI between 18.5-24.9 kg/m² – Place in Group B. If Total Points (12-A + 12-B) = $\leq$ 12 and have BMI between 25-39.9 kg/m² – Place in Group C. If Total Points (12-A + 12-B) = $>$ 12 and have BMI between 25-39.9 kg/m² – Place in Group D.
--

Circle appropriate recruitment box for participant.

Group A (n = 16)	Group B (n = 16)	Group C (n=16)	Group D (n = 16)
BMI: 18.5-24.9 kg/m ² DR Score: $\leq$ 12	BMI: 18.5-24.9 kg/m ² DR Score: $>$ 12	BMI: 25-39.9 kg/m ² DR Score: $\leq$ 12	BMI: 25-39.9 kg/m ² DR Score: $>$ 12

Is recruitment box full? Look at EXCEL spreadsheet to determine numbers in each recruitment box.

☐ No

☐ Yes (**INELIGIBLE**)

If recruitment box is full: I’m sorry, based on information you have provided, you are not eligible for this study. Thank you for your interest.

IF ELIGIBLE: Congratulations! I am happy to tell you that you meet the eligibility criteria for the Snack Food Impact Study. I'd like to schedule you for an appointment. We are scheduling initial appointments on Thursdays and Fridays from 8AM until 8PM. We are also scheduling follow-up appointments four days from your initial appointment, which means you will need to come in on the subsequent Monday or Tuesday at a time similar to the time you arrive on the preceding Thursday or Friday.

Which day and time works best for you for your initial appointment? (Review schedule for available appointments.)

We have ---- (day), ---- (date) at ---- (time). Does that work for you?

This means you will need to come back for your 10-minute follow-up appointment on...

---- (day), ---- (date) at ---- (time). Does that work for you?

If initial appointment is scheduled on Thursday, come back Monday; if initial appointment is scheduled on Friday, come back Tuesday. Time scheduled must be between a 2-hour time frame of when the initial appointment is scheduled.

Before confirming -- ASK: Are you planning on going on a vacation (out-of-town) during the 4-day period that you will be required to take the box of snack food home with you? **If yes:** reschedule to a time when participant will **not** be going out of town.

Initial appointment: Thursday or Friday (circle day), _____ (date) at _____(time)

Follow-up appointment: Monday or Tuesday (circle day), _____ (date) at _____ (time)

The HEAL Lab is located in the Jessie Harris Building, Room 102. Do you know where that is? (If no, provide directions. JHB is located on Cumberland Ave and 12th Ave, next to the 11th Ave parking garage. The UTK website has a building locator if needed.)

We have you scheduled for your initial appointment on ---- (day), ---- (date) at ----(time). Your appointment will take about 30 minutes. Please arrive on time as we may have another appointment scheduled immediately after yours.

We will send you an email confirming your appointment. If for some reason you cannot keep your appointment, please call our lab at (865) 974-0754. Thanks for participating in our study!

First Name: _____ Last Name: _____ Home Address: _____ _____ Email Address: _____ Phone # 1: _____ mobile/home/other Phone # 2: _____ mobile/home/other	
Eligible: ☐ No ☐ Yes If No, Reason: _____ Appointment Date: ____/____/____ Time: ____ Follow-Up Date: ____/____/____ Time: ____	Screened by: _____ Date: _____ Recruitment Box (circle one): A B C D Condition #: 1 2

Enter participant information on PTL.

INFORMED CONSENT STATEMENT

Snack Food Impact Study

Name of Participant

INTRODUCTION

You are invited to participate in a research study. The purpose of the study is to investigate the effect of recent snack food consumption on liking of snack foods. Chrystal Haire is conducting this research study to fulfill requirements of her Master's thesis.

INFORMATION ABOUT PARTICIPANT INVOLVEMENT IN THE STUDY

You have been asked to participate in this study because you are an adult between the ages of 18 and 35, you are not underweight, and you have no medical conditions, which would indicate that you should not participate in this investigation. A total of 64 people will participate in this study. This study involves two brief in-lab sessions. If you choose to participate in this study, you will be asked to attend both sessions.

Session One

You will attend an *initial 30-minute session* in the Healthy Eating and Activity Laboratory (HEAL) on either Thursday or Friday. During this session, height and weight measures will be taken. You will then be given a form asking you to rate your liking of a particular snack food (pretzels). In addition, you will be given a box of pretzel packages to take home for a period of four days. You will either be given a box of two, 10.0-ounce packages of pretzels or a box of twenty-two, 0.9-ounce packages of pretzels. During this 4-day period, you will need to refrain from sharing the provided pretzels with others. You will also need to at least taste the pretzels, but can eat as little or as much as you desire. Additionally, you will be given a brief form to fill out during this time period documenting when (date/time) and where you consumed the pretzels. Prior to leaving, you will be reminded of the date and time of your second 10-minute session that you must attend four days from the initial session (which will either be on a Monday or Tuesday depending on which day you come in for your initial session).

Session Two

At the second session, you will bring back all pretzel packages, including packages that have been opened or emptied. You will also bring back the completed form documenting when (date/time) and where you consumed the provided pretzels. In addition, you will once again be asked to rate your liking of the provided snack food (pretzels). *This session will take 10 minutes.*

Please call Chrystal Haire at (865) 974-0754 if you have any questions about these procedures for the study.

RISKS

The risks of participating in this study are small. If you are allergic to the snack food given to you to take home during the study period, you may have an allergic reaction. However, the snack food used in this study is a common snack food, and all participants are asked about food allergies during the initial eligibility screening process.

BENEFITS

Participants will receive no benefits from participation in this research study.

CONFIDENTIALITY

The information in the study records will be kept confidential. Participants will be given a unique identification number that will be used on all documents with no references to individual names, addresses, or phone numbers. Data will be stored securely in locked filing cabinets and in password-protected electronic files in Room 102 in the Jessie Harris Building. Data will be made available only to persons conducting the study, unless participants specifically give permission in writing to do otherwise. No reference will be made in oral or written reports which could link participants to the study.

COMPENSATION

You will receive a \$10 gift card after completing all of the study requirements, including attending the two in-lab sessions.

EMERGENCY MEDICAL TREATMENT

The University of Tennessee does not "automatically" reimburse subjects for medical claims or other compensation. If physical injury is suffered in the course of research, or for more information, please notify the investigator in charge, Chrystal Haire, at (865) 974-0754.

CONTACT INFORMATION

If you have questions at any time about the study or the procedures (or you experience adverse effects as a result of participating in this study), you may contact the investigator in charge, Chrystal Haire, at the Department of Nutrition, Jessie Harris Building Room 102, the University of Tennessee, Knoxville, TN 37996, or at (865) 974-0754. If you have questions about your rights as a participant, contact the Office of Research Compliance Officer at (865) 974-3466.

PARTICIPATION

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

CONSENT

I have read the above information. I have received a copy of this form. I agree to participate in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

Date: _____

PID #: _____

Anthropometric Measures

Height: _____ inches

Weight: _____ pounds

BMI: _____ kg/m²

Date: _____

Demographics Questionnaire

1. AGE _____

2. SEX: ☐ MALE ☐ FEMALE
(1) (2)

3. EDUCATION: Check years of school completed. (CHECK ONLY ONE ANSWER)

- ☐ (1) Grade School (6 yrs or less)
☐ (2) Junior High School (7-9 yrs)
☐ (3) High School (10-12 yrs)
☐ (4) Vocational Training (beyond High School)
☐ (5) Some College (less than 4 yrs)
☐ (6) College/University Degree
☐ (7) Graduate or Professional Education

4. MARITAL STATUS:

- ☐ (1) Married
☐ (2) Separated
☐ (3) Divorced
☐ (4) Widowed
☐ (5) Never Married
☐ (6) Not Married (living with significant other)
☐ (7) Other (specify): _____

5. Which of the following best describes your racial heritage? (you may choose more than one)

- ☐ (1) American Indian or Alaskan Native
☐ (2) Asian
☐ (3) Black or African American
☐ (4) Native Hawaiian or other Pacific islander
☐ (5) White
☐ (6) Other (specify): _____

6. Which of the following best describes your ethnic heritage?

- ☐ (1) Hispanic or Latino
☐ (2) Not Hispanic or Latino

DATE //
M M D D Y Y

Office Use Only

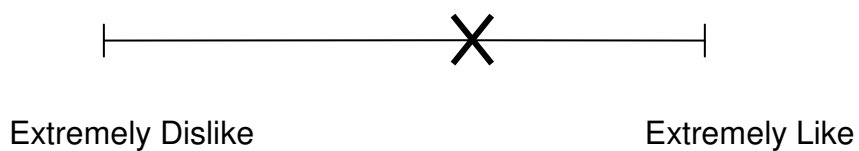
PID #:

Date:

Visual Analogue Scale of Pretzels

On the blank line provided, please draw an 'X' to indicate your degree of liking of pretzels:

EXAMPLE: Vanilla Ice Cream



PRETZELS



Official Use Only:

Score: _____

Office Use Only	
PID #:	
Date:	

Date:

[illegible]

Instruction Reminders

- **You must at least taste the provided pretzels during the 4-day study period, but you can eat as little or as much as desired.**
- **Do not share provided pretzels with others.**
- **Each time you eat the provided pretzels, be sure to fill out the Self-Report of Pretzel Consumption form.**
- **When you come to your second session appointment, bring back ALL pretzel packages.**
 - **This includes unopened, opened, or emptied packages – BRING BACK EVERYTHING.**

Second Session Appointment Reminder

Your second session appointment is on

Date: _____

Time: _____

Questions or Concerns? Please call the Healthy Eating and Activity Laboratory and ask for Chrystal Haire, the investigator in charge of the Snack Food Impact Study. Number: (865) 974-0754.

Participant Compensation Form

Thank you for your participation in the Snack Food Impact Study. Because you have completed all study requirements, including attending the two in-lab sessions, you will receive a \$10 gift card as compensation for your time and effort. Please complete the following information in order to document the receipt of your gift card:

Signature: _____

Printed Name: _____

Address: _____

VITA

Chrystal Haire was born and raised in Rock Hill, South Carolina. She received a Bachelor of Science degree in Food Science (Nutrition and Dietetics Concentration) from Clemson University in May of 2010 with a 4.0 on a 4.0 scale. While an undergraduate student, Chrystal worked closely with the Catawba Indians, acting as a nutrition educator at the Catawba Cultural Center Summer Camp and a summer dietetic intern at the Catawba Service Unit (Indian Health Service). It was through this experience that Chrystal developed an interest in and passion for diabetes care and education. In August of 2010, she went on to continue her education at the University of Tennessee-Knoxville, pursuing a Master of Science degree in Nutrition with a concentration in Public Health Nutrition and a Master of Public Health degree with a concentration in Community Health Education. While at the University of Tennessee, Chrystal has served as a Graduate Teaching Assistant for two undergraduate senior-level nutrition courses, as well as a Student Research Assistant in the Healthy Eating and Activity Laboratory. Chrystal plans to complete a dietetic internship at the University of Tennessee and graduate with a dual degree in May of 2013. Long-term plans of hers include working in the field of diabetes care and education as a Registered Dietitian and a Certified Diabetes Educator.