NOVEL SCHOOL-BASED STRATEGIES TO IMPROVE PARTICIPATION IN THE SCHOOL BREAKFAST PROGRAM, DIET QUALITY, AND COGNITIVE PERFORMANCE IN ADOLESCENTS

by

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Dr. Michele Forman Head of the Graduate Program I dedicate all my work to my savior Jesus Christ, my Lord and savior, and my parents, brothers, mentors, and fiancée Sarah who all have made countless sacrifices for my successes.

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ABSTRACT

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Observational evidence links breakfast skipping, a behavior frequently observed among adolescents, with other poor health related behaviors that perpetuates a lifestyle associated with poor weight management and decreased cognitive performance. Furthermore, evidence suggests that both the consumption of breakfast and the quality of breakfast consumed may influence both weight and cognitive performance related outcomes. In an effort to improve the prevalence of breakfast consumption and the quality of breakfasts consumed among adolescents, recent initiatives have sought to increase participation in the federal School Breakfast Program (SBP).

The main objectives of this dissertation were to determine: 1) whether the habitual consumption of breakfast influences perceived appetite following the consumption of breakfast and whether habitual breakfast consumption influences post prandial appetitive sensations following the consumption of breakfasts varying in macronutrient distribution; 2) the feasibility of consuming an egg-based, 'Breakfast in the Classroom' (BIC) program in 8th grade students and whether the daily consumption of egg-based breakfasts improve School Breakfast Program participation, the quality of breakfasts consumed, and snacking behavior in 8th grade students; and 3) whether differences in cognitive performance exist between 6th-8th grade students who consume school breakfast, students who consume breakfast at home only, and students who skip breakfast following the initiation of a higher-protein Breakfast in the Classroom program.

This dissertation is organized into chapters that consist of published manuscripts or manuscripts formatted for submission to peer-reviewed journals. Chapter 2 consists of comprehensive review of the evidence linking breakfast consumption and composition to obesity and cognitive performance with an emphasis on the recent advances in school breakfast programs and future directions. Chapter 3 evaluates whether the habitual consumption of breakfast influences perceived appetite following the consumption of breakfast and whether habitual breakfast consumption influences postprandial appetitive sensations following the consumption of breakfasts varying in macronutrient distribution. Chapter 4 examines the feasibility of implementing an egg-based BIC program and subsequent effects on SBP participation, the quality of breakfasts consumed, and evening snacking in 8th grade students. Chapter 5 examines differences in cognitive performance between 6th-8th grade students who consume school breakfast, students who consume breakfast at home only, and students who skip breakfast following a higher-protein BIC. Chapter 6 summarizes the main findings and presents considerations for future research.

Collectively, the findings from this dissertation demonstrate:1) consuming 30 grams of protein at breakfast improves appetite and satiety compared to a breakfast containing 15 grams of protein, independent of habitual breakfast consumption in overweight adolescent females; 2) implementing a universally-free 'Breakfast in the Classroom' program that serves two additional eggs to a traditional school breakfast served via a traditional SBP is feasible and improves SBP participation, the quality of breakfast consumed, and reduces unhealthy evening snacking; and 3) students who consume breakfast at school, as part of a higher-protein BIC program, perform better on tasks assessing cognitive flexibility and executive function in middle school students when compared to students who skip breakfast, regardless of key behavioral and/or socioeconomic factors. Thus, this work suggests increasing protein content of school breakfasts using a universally-free distribution program is feasible and may provide benefits on overall diet quality and cognitive performance for 6th-8th grade students.

CHAPTER 1. INTRODUCTION

1.1 Dissertation Rationale

Breakfast skipping, particularly in young people, has been linked with an increased prevalence of unhealthy eating patterns (i.e., increased high fat/high sugar snacking with reductions in fruit, vegetable, and dairy consumption), weight gain, and obesity (1-5). The associative evidence demonstrate a significant positive relationship between breakfast skipping and obesity with a p-value of 10^{-42} (1). Although still controversial, breakfast consumption increases satiety primarily via hormones commonly associated with reductions in energy intake when compared to skipping breakfast (6-8). Specifically, ingestive behavior related hormones, such as peptide YY (PYY) and ghrelin, are often considered regulators that mediate the length of time between subsequent eating occasions (6-9). To accompany these ingestive behavior related hormones, subjective measures assessing perceived appetite are used to supplement the findings observed in studies assessing the response of the aforementioned hormones to specific meal challenges. These values are sometimes used to suggest a modest predictive value on subsequent food intake (10, 11), albeit somewhat inconsistently (12). Recently researchers have begun to recognize a potential role of breakfast composition on subsequent indices of weight management and weight management related outcomes. Specifically, in an acute randomized controlled trial conducted in our lab, twenty overweight or obese breakfast skipping adolescents were recruited to continue skipping breakfast, consume a breakfast with macronutrients matching a typical American's breakfast, or consume an isocaloric, higher-protein breakfast on three separate days (9). In this study, the consumption of the higher-protein breakfast increased satiety and reduced evening consumption of high-fat snacks compared to skipping breakfast in habitual breakfast skippers (9).

Beyond consideration for acute breakfast consumption and breakfast composition (3), a growing number of studies have begun to highlight the importance of breakfast skipping habits on appetitive and/or metabolic responses to breakfast (8, 13). Specifically, Alwattar et al. reported that habitual breakfast consumption influenced differences in glucose concentrations when comparing glucose concentrations throughout the day following the consumption of a higher protein vs a normal protein breakfast (13). Specifically, habitual breakfast skippers experienced greater glucose concentrations following the consumption of a higher protein breakfast when compared with habitual breakfast consumers. Schlundt et al. suggests that the changes in weight following a long-term term breakfast intervention is dependent on habitual breakfast consumption, such that the most dramatic effects on weight are observed when habitual consumers skip breakfast or when skippers consume breakfast (14). One characteristic lacking in the current literature includes examining whether other hormonal responses, such as those related to ingestive behavior, are dependent on the interaction between the macronutrient composition of breakfast and habitual breakfast habits.

The consistent associations between breakfast skipping and negative health outcomes, in addition to the observed increase in breakfast skipping behavior, have led to an urgent need to develop and/or improve strategies that increase breakfast consumption. In 2010, Healthy People 2020 gathered as a group of non-federal, independent experts to provide science-based objectives for improving the health of all Americans over the next 10 years (15). One of those objectives includes a focus on expanding a healthier school breakfast program. Progress from this initiative was pushed to the forefront by the 'Healthy, Hunger-Free Kids Act' that sought to provide schools with toolkits to improve school meals, offer more fruits and vegetables, reduce the sodium content of foods, and serve whole grains in school meals (16). In line with the objectives of Healthy People

2020 and the 'Healthy, Hunger-Free Kids Act,' national education and nutrition organizations have begun collaborating to improve the School Breakfast Program (SBP).

Originally, traditional school breakfast programs were implemented to improve the nutrition available for children who might otherwise not be able to afford breakfast in the home. Although there are a number of benefits associated with SBP participation (i.e. lower obesity rates (17) and improved cognitive/academic performance (18, 19)), less than one-third of enrolled students participate (20, 21). Furthermore, although ~12 million children who are eligible for free/reduced meals currently participate in school breakfast programs (20), that amount is only half of the eligible children. Reasons for the lack of participation in the programs include poor food quality, the lack of awareness, limited school time to eat the breakfast, late bus schedules, weight concerns, and negative stigmas with eating in the cafeteria (22-26). Recently, 'Breakfast in the Classroom' (BIC) was developed as an attempt to alleviate some of the previously stated limitations to improve school breakfast program participation.

BIC offers a number of innovative ways to provide breakfast to students outside of the cafeteria setting. These include breakfast delivery directly to the classroom, 'grab-and-go' hallway kiosks, etc. Recent evidence has illustrated that the implementation of BIC increased school-based breakfast participation by at least 2-fold (27-29). Furthermore, as previously mentioned, improvements in satiety, reductions in snacking and daily food intake, and the prevention of body fat gain have been demonstrated following the addition of breakfast in overweight teens who habitually skip breakfast (9, 30). Although these effects are primarily observed when the breakfast consumed is rich in high quality protein, these observations are not exclusive to higher protein breakfasts. In a recent cluster randomized controlled trial of almost 4,000 elementary school students, Ritchie et al observed that students attending schools participating in BIC consumed a

higher quality diet, as calculated by the Healthy Eating Index 2010, when compared to students attending schools that did not participate in BIC (31). This observation was a result of increased fruit and vegetable intake, not decreased unhealthy evening snacking as observed in our aforementioned higher-protein breakfast studies. However, no study to our knowledge has implemented a higher-protein SBP intervention to examine whether evidence observed in clinical studies (i.e. reduced evening snacking) extends to a school-based environment. Some of the challenges faced when attempting to consume a high-protein breakfast at home includes the reduced number of family meals during the breakfast time (partly due to the reduced time in the morning allotted to prepare meals), the increased cost of protein-rich foods, and lack of availability of protein-rich foods. Thus, an ideal alternative to alleviate the aforementioned issues is the delivery of a protein-rich breakfast through the SBP. *However, to support sound recommendations, the feasibility and the relative effectiveness of a protein-rich breakfast compared to a traditional school breakfast program on SBP participation and overall dietary quality must still be evaluated.*

The benefits of consuming breakfast extend beyond improvements in overall health and well-being, there are also notable improvements in cognitive performance. Compared to when breakfast was skipped, breakfast consumption appears to improve attention (32-37), memory (37-39), and executive function (34, 35, 38, 40). Therefore, a recent review sought to characterize the gaps in the literature to explain the discrepant findings (41). According to the recommendations of this review, designing a study to assess the role of breakfast consumption on cognitive performance should give special consideration to the ecological validity of the study (i.e. school-based setting), the socioeconomic status of the students, and timing of the cognitive assessments (late-mid morning) (41). *Although some data exist exploring the improvements in cognitive performance*

as a result of SBP adoption, a paucity of literature exists evaluating individual performance based on acute breakfast consumption in a school-based setting with consideration for habitual SBP participation, SES, and perceived appetite & well-being.

1.2 Dissertation Objectives

The main objectives of this dissertation are to:

- Determine whether the habitual consumption of breakfast influences perceived appetite following the consumption of breakfast and whether habitual breakfast consumption influences postprandial appetitive sensations and ingestive behavior related hormones following the consumption of breakfasts varying in macronutrient distribution.
- Determine the feasibility of consuming an egg-based, 'Breakfast in the Classroom' program in 8th grade students and whether the universally free, BIC that serves egg-based breakfasts daily improves school breakfast program participation, the quality of breakfasts consumed and snacking behavior in 8th grade students.
- Determine whether students who consume breakfast at school, as part of a universally free BIC program, perform better on tasks assessing cognitive performance when compared to breakfast consumption at home only and skipping breakfast and whether differences are driven by appetite & well-being, socioeconomic status, and/or habitual SBP participation in 6-8th grade students following the initiation of BIC.

1.3 Organization of Dissertation

This dissertation is organized into chapters that consist of manuscripts submitted for peerreview or manuscripts formatted for submission to peer-reviewed journals. Details pertaining to the status of each manuscript are included at the beginning of each chapter. Chapter 2 consists of a comprehensive review of the evidence linking breakfast consumption and composition to obesity and cognitive performance with an emphasis on the recent advances in school breakfast programs and future directions. This chapter serves to identify and discuss gaps in the current literature while providing background for the subsequent chapters.

Chapter 3 evaluates whether habitual breakfast consumption behavior influences postprandial appetitive sensations and ingestive behavior related hormones following the consumption of breakfasts varying in macronutrient distribution.

Chapter 4 examines the feasibility of implementing an egg-based BIC program in 8th grade students. As a secondary outcome, the influence of an egg-based 'Breakfast in the Classroom' program on SBP participation, the quality of breakfasts consumed, and snacking behavior were also evaluated.

Chapter 5 examines whether 6th-8th grade students who consume school breakfast, when compared to consuming breakfast at home only and skipping breakfast, perform better on tasks assessing cognitive performance following the initiation of a higher-protein BIC. As a secondary outcome, the influence of habitual SBP participation, socioeconomic status, and appetite and wellbeing were evaluated as potential factors for cognitive performance in 6-8th grade students.

Chapter 6 summarizes the main findings and presents considerations for future research.

1.4 Dissertation Aims and Hypotheses

Chapter 3:

Specific Aim 1: to examine whether differences in postprandial appetite and hormonal responses following the consumption of a normal protein breakfast versus a higher protein breakfast are dependent on habitual breakfast habits in overweight adolescents who habitually consume breakfast compared to those who habitually skip breakfast.

Hypothesis 1a: Changes in postprandial appetite following the consumption of a normal protein versus a higher protein breakfast will be independent of habitual breakfast habits in overweight adolescents who habitually consume breakfast compared to those who habitually skip breakfast. <u>Approach</u>: Repeated assessments of appetite and satiety measures will be conducted during a tightly controlled clinical testing day.

Hypothesis 1b: Changes in ingestive behavior related hormonal responses following the consumption of a normal protein versus a higher protein breakfast will be independent of habitual breakfast habits in overweight adolescents who habitually consume breakfast compared to those who habitually skip breakfast. <u>Approach</u>: Repeated assessments of appetite and satiety measures will be conducted during a tightly controlled clinical testing day.

Chapter 4:

Specific Aim 1: To determine the feasibility of implementing a universally-free 'Breakfast in the Classroom' program that serves a traditional school breakfast with the addition of two eggs for 8th grade students in a school-based setting.

Hypothesis 1: It will be feasible to implement a universally-free 'Breakfast in the Classroom' program that serves a traditional school breakfast with the addition of two eggs for 8th grade students in a school-based setting. <u>Approach</u>: We will work with the food service director of Center Middle School to develop methods to cook and distribute two additional eggs to each breakfast and to serve breakfast to all 8th graders.

Specific Aim 2: To test whether the implementation of a universally-free 'Breakfast in the Classroom' program that serves a traditional school breakfast with the addition of two eggs versus a traditional School Breakfast Program serving a traditional school breakfast improves School Breakfast Program participation, breakfast consumption, and snacking behavior in 8th grade students.

Hypothesis 2a: A universally-free 'Breakfast in the Classroom' program that serves a traditional school breakfast with the addition of two eggs will improve school breakfast participation compared to a traditional school breakfast program. <u>Approach</u>: Questionnaires asking participants about habitual breakfast habits, including school breakfast program participation, will be administered prior to the universally-free 'Breakfast in the Classroom' program and two weeks following the program's implementation. School Breakfast Program participation will also be tracked using the school's Point-of-Sale system.

Hypothesis 2b: A universally-free 'Breakfast in the Classroom' program that serves a traditional school breakfast with the addition of two eggs will improve the quality of the breakfast consumed at school when compared to a traditional school breakfast program. <u>Approach</u>: Questionnaires asking participants about habitual breakfast habits, including habitually consumed breakfast foods, will be administered prior to the universally-free 'Breakfast in the Classroom' program and two weeks following the program's implementation. Hypothesis 2c: A universally-free 'Breakfast in the Classroom' program that serves a traditional school breakfast with the addition of two eggs will reduce unhealthy evening snacking compared to a traditional school breakfast program. <u>Approach</u>: Questionnaires asking participants about habitually consumed snack foods will be administered prior to the universally-free 'Breakfast in the Classroom' program and two weeks following the program's implementation.

Chapter 5:

Specific Aim 1: To evaluate whether those who consume breakfast at school, as part of a universally free 'Breakfast in the Classroom' program, perform better on tasks assessing cognitive performance when compared to students who consume breakfast at home and students who skip breakfast in the $6^{\text{th}}-8^{\text{th}}$ grade.

Hypothesis 1: Students who consume breakfast, regardless of the location of breakfast consumption, will perform better on tasks assessing cognitive performance when compared to 6th-8th grade students who skip breakfast. <u>Approach</u>: Online neurocognitive assessments of cognitive performance will be administered following the implementation of the universally-free 'Breakfast in the Classroom' program. These assessments will assess visual memory, reaction time, cognitive flexibility, processing speed, and executive performance.

Specific Aim 2: To test whether cognitive performance following the initiation of a universally free 'Breakfast in the Classroom' program is influenced by an interaction between acute breakfast consumption and habitual breakfast consumption in 6th-8th grade students.

Hypothesis 2: Students who habitually consume breakfast at school, as part of a universally free 'Breakfast in the Classroom' program and consume the breakfast the morning of their cognitive performance assessment will perform better on tasks assessing cognitive performance when compared to 6th-8th grade students who habitually skip breakfast and skip breakfast the morning of the assessment. <u>Approach</u>: Daily participation in the program will be determined by an electronic tracking system implemented by the school to track breakfast participation.

Specific Aim 3: To test whether cognitive performance following the initiation of a universally free 'Breakfast in the Classroom' program is influenced by an interaction between acute breakfast consumption and socioeconomic status in $6^{\text{th}}-8^{\text{th}}$ grade students.

Hypothesis 3: 6th-8th grade students who consume breakfast, as part of a universally free 'Breakfast in the Classroom' program, the morning of their cognitive performance assessment and qualify for free/reduced meals will perform better on tasks assessing cognitive performance when compared to their breakfast skipping, free/reduced meal eligible peers who skip breakfast. <u>Approach</u>: Free/reduced meal eligibility will be determined using a report, lacking personally identifiable information that is collected as part of an electronic tracking system implemented by the school to track breakfast participation for reimbursing the meals based on students' free/reduced meal eligibility.

Specific Aim 4: To test whether cognitive performance following the initiation of a universally free 'Breakfast in the Classroom' program is influenced by an interaction

between acute breakfast consumption and measures of appetite and well-being in $6^{th}-8^{th}$ grade students.

Hypothesis 4: Students consume breakfast as part of a universally-free 'Breakfast in the Classroom' program, will perform better on tasks assessing cognitive performance, be less hungry and more full when compared to skipping breakfast in $6^{th}-8^{th}$ grade students. <u>Approach</u>: Paper questionnaires assessing appetite and well-being will be completed immediately before the cognitive performance assessment using a 100 mm visual analog scale.

1.5 References

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CHAPTER 2. A REVIEW OF SCHOOL BREAKFAST PROGRAMS AND THEIR EFFECTS ON WEIGHT MANAGEMENT, DIET QUALITY, AND COGNITIVE PERFORMANCE – A FOCUS ON NOVEL SCHOOL BREAKFAST PROGRAMS

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Abbreviations: BIC, Breakfast in the Classroom; GLP-1, Glucagon-like Peptide-1; PBIC, Partners for Breakfast in the Classroom; PYY, Peptide YY; RTEC, Ready-to-Eat Cereals; SBP, School Breakfast Program; USDA, United States Department of Agriculture

2.1 Abstract

Skipping breakfast is consistently linked with a number of health-related comorbidities along with impaired performance on tasks assessing attention, executive function, and memory. The increasing trend of breakfast skipping is particularly troubling among children and adolescents, with a greater prevalence reported among low socioeconomic status adolescents. Thus, recent initiatives to improve School Breakfast Program (SBP) participation have been created to combat the high prevalence of breakfast skipping behavior. Currently, only about one-fourth of the total number of enrolled students participate in a SBP and only half of students who qualify for free/reduced price meals are participating. To improve school breakfast participation, a number of novel school-based programs have been developed, including, but not limited to, 'Breakfast in the Classroom' (BIC). The purpose of this review is to discuss the role of breakfast consumption on indices of weight management and cognitive performance with a focus on school breakfasts and novel SBPs designed to improve school breakfast participation. Among the novel SBP's reviewed, studies evaluating the effectiveness of BIC are most prevalent. BIC consistently increases school breakfast participation and may serve as an avenue to improve overall diet quality. However, limited data exists elucidating the role of SBP participation on weight management, particularly in schools utilizing BIC or other novel programs. In regard to cognitive performance, schools utilizing BIC demonstrate improved math and reading achievement scores. However, limited data exists evaluating cognitive performance before and after the initiation of BIC. Thus, future studies should be conducted within schools implementing BIC to evaluate the role of school-based breakfast participation within BIC or other novel programs on weight management and cognitive performance.

2.2 Keywords

School Breakfast Program, Breakfast, Appetite, Weight Management, Cognitive Performance, Breakfast in the Classroom

2.3 Introduction

Skipping breakfast in the morning is consistently linked with a number of health-related comorbidities (1-5). Observational evidence demonstrate a strong association between breakfast skipping and obesity, with a p-value of 10⁻⁴² (3). In addition, among school-aged children and adolescents, skipping breakfast also impairs attention (6-11), memory (11-13), and executive function (8, 9, 12, 14) relative to those who consume breakfast. In studies that stratify by nutrient status, children and adolescents who are undernourished/impoverished experience these impairments to a more significant extent (15-17). Given the benefits of breakfast consumption on health and well-being in young people, the current prevalence of breakfast skipping is particularly troubling. According to What we Eat in America, derived from 2015-2016 NHANES Dietary Interviews, approximately 26% of adolescents reported not consuming breakfast (18). This prevalence increases to 31% among adolescents whose family income is less than 131% poverty level (18). Thus, the implementation of School Breakfast Programs (SBP) is one strategy to promote breakfast consumption, particularly in those who may not be able to afford adequate nutrition at home.

Although approximately 15 million children and adolescents in the United States participated in SBP during the 2017-2018 school year, this is approximately one-fourth of all students in the public school systems (approximately 57 million) (19, 20). Also alarming is the fact that only about half of the students (approximately 12 million) who qualify for free/reduced school meals actually participate in the program (19). Thus, recommendations have been

developed 1) to increase the proportion of schools with a school breakfast program (21); 2) to improve participation by improving the quality of foods served; and 3) to develop unique approaches to serving breakfast within the school setting (22-24).

The purpose of this review is to discuss the role of breakfast consumption on indices of weight management and cognitive performance with a focus on school breakfast and novel SBPs designed to improve school breakfast participation.

2.3.1 Historical Background of the School Breakfast Program

The initiation of the SBP began in 1966 as a pilot project to improve the nutrition of children and adolescents who may be unable to acquire proper nutrient requirements at home based on their parent's income (25). The SBP provides federally subsidized breakfasts to children in need and continues to evolve in order to promote weight management and improve cognitive performance. The SBP supplies cash subsidies for school districts and independent schools for each meal they serve, pending that the meals meet the Federal requirements for a reimbursable meal (**Supplemental Table 1**) and they offer free or reduced prices for children who are eligible (**Supplemental Table 2**) (23, 26-28).

In 1975, the program was made permanent and participation began to grow (25). Participation rates were relatively low (~23%) throughout the early years of the program. Extraneous factors, such as community attitudes toward the schools versus the families' role in feeding children, may have influenced school breakfast participation during this period of time (29). As acceptance of the program grew, an increasing proportion of students (~37%) began consuming meals outside of their traditional home environment (25, 30, 31).

From 1975 until 1991, significant trends in breakfast foods consumed among U.S. households also changed. By 1991 the consumption of bacon, egg, butter, margarine, and white

bread decreased, suggesting a trend away from the typical eggs, bacon, and toast breakfast (30). Instead, the typical breakfast was substituted with the consumption of whole-grains, lower-fat milk, quick breads, and ready to eat cereals (30). This reflects a changing family dynamic, a shift in consumption towards more convenient foods for busy families (25). The change in foods consumed was accompanied by a concerning revelation amongst those studying the effects of the SBP. Specifically, it became evident that those who received the reimbursable meals were deficient in vitamin A, vitamin B6, niacin, thiamin, and iron compared to their aged-matched counterparts (32). Thus in 1994, the nutrition standards for school breakfasts, averaged over a week, changed to include limit the calories to 25% of the Recommended Dietary Allowance (RDA), at least onethird of the RDA for key nutrients (protein, calcium, iron, vitamin A, and vitamin C), no more than 30% of the calories derived from fat, no more than 10% of the calories derived from saturated fat, reduced sodium and cholesterol (no quantifiable regulation), increased dietary fiber (no quantifiable regulation), and overall at least an entrée, fluid milk, and one other item (to qualify as a meal) (33). Following this legislative change, a subsequent study observed a positive trend such that many of the aforementioned deficiencies were mitigated (34). However, compared to matched nonparticipants, participants in SBP were still deficient in vitamin A and phosphorous despite consuming excess quantities of sodium (34).

Although minor changes were made between 2000 and 2004, significant changes were not enacted again until the Healthy, Hunger Free Kids Act in 2010 (22, 23). Funding, as a result of the Healthy, Hunger Free Kids Act, was released to the United States Department of Agriculture (USDA) to assess and improve school meals. The revised requirements for reimbursable school breakfasts were set, and continue to be regulated, by the USDA to include at least one cup of fruit, one cup of whole-grain rich foods, and one cup of milk per day (5 cups of fruit, 7-10 oz equivalents of grains, and 5 cups of milk per week respectively) (22, 26, 27, 35). Although evaluation of the subsequent changes in the nutrition status of students participating in the SBP is ongoing, current evidence suggests these standards have improved overall dietary patterns by increasing foods consumed such as fruit juice (meeting the fruit requirement), milk, and whole grains (via cereal) (36). The current nutrient disparities across the country and the relative positive impact of school breakfast programs suggest that this platform is an ideal target for nutrition initiatives aimed at reducing the prevalence of diet-related public health concerns, such as the obesity epidemic.

2.4 Non-school Based Breakfast Interventions and Indices of Weight Management

Only two long-term invention studies exist that target weight management in children/adolescents (37, 38). The first study by Rosada JL, et al. (37) was a randomized controlled trial designed to determine if ready-to-eat cereals (RTEC), with and without nutrition education, reduce excess body weight gain. Previous evidence suggests that the inclusion of RTEC is one strategy to reduce dietary fat intake by increasing the carbohydrate to fat ratio of their diet, even in the absence of nutrition advice (39). Thus, in this study, 147 overweight children were evenly assigned to the following groups for twelve weeks: 1) one serving of RTEC for breakfast/d; 2) one serving of RTEC at breakfast/d and one serving of RTEC at dinner/d; 3) one serving of RTEC for breakfast/d plus nutrition education; or 4) no intervention which served as the control (37). After 12 weeks, only those who received the RTEC for breakfast with nutrition education had lower body weight (-1.01 (-1.69,-0.34)) and BMI (-0.95 (-1.71,-0.20)) when compared to the control group (1.19 (0.39,1.98) and 0.01 (-0.38,0.41), respectively). These findings suggest that breakfast consumption with nutrition education may be an effective strategy to promote weight management in young people. It is important to note that the study did not screen out for habitual breakfast consumption. Thus, this study may have included habitual breakfast consumers, who consumed

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any type and amount of breakfast (prior to the intervention), and habitual breakfast skippers. Thus, it is unclear whether changing habitual breakfast habits or breakfast food types influenced the overall findings.

Evidence continues to grow illustrating positive effects of increased protein consumption for weight management (See review by Leidy et al., (40)). Recently, a number of studies have suggested that protein timing, particularly at breakfast, may influence a number of health-related outcomes in young people (41-44). With respect to changes in body weight and composition, we previously completed a 12-week randomized controlled trial in 57 breakfast skipping overweight/obese adolescents. The participants either continued to skip breakfast or consumed normal-protein (13 g protein) or high-protein (35 g protein) breakfasts each morning for 12-weeks (38). Changes in body composition were assessed at baseline and at the end of the 12-week period. Although changes in body weight were not detected between groups, the higher-protein breakfast group had less body fat gain over the 12-week period compared those who continued to skip breakfast. These improvements were not observed in those consuming the normal-protein breakfasts. As evidence continues to grow regarding the role of protein on weight management, future recommendations regarding breakfast consumption in school-aged children will likely include consideration for additional protein at breakfast and nutrition education.

The consumption of breakfast has also been shown to positively alter ingestive behavior in adults (see review by Gwin et al., (45)). Using visual analog scale-based questionnaires, the consumption of breakfast reduces hunger and increases fullness compared to skipping the morning meal (4, 45). Further, breakfast consumption, in some studies, also increases the satiety hormones, Peptide YY (PYY) and Glucagon-like Peptide-1 (GLP-1), compared to skipping breakfast (46-48). Although debate still exists, increased concentrations of PYY and/or GLP-1 serve as ingestive

behavior regulators that prolong subsequent eating initiation, particularly when observed in conjunction with other appetitive hormones (41, 46-48). The observed changes in these hormones are often accompanied by reductions in hunger and increased fullness following the consumption of breakfast (41, 46, 49).

Studies evaluating the effects of breakfast quality on appetite control support consideration for the consumption of higher-protein breakfasts. Although limited evidence exists, when comparing postprandial differences in the protein/carbohydrate distribution of breakfasts, improvements in subjective feelings of appetite were observed following the consumption a highprotein breakfast versus an isocaloric lower protein breakfast when both are compared to breakfast skipping (38, 41, 42, 44). Specifically, Leidy HJ and Racki EM recruited thirteen breakfast skipping adolescent males who completed three testing days, in a randomized order, that included the consumption of a normal protein breakfast (18g), a higher protein breakfast (48g), or continued to skip breakfast. In this study, the consumption of breakfast, regardless the macronutrient composition, increased fullness throughout the morning postprandial period. However, only the consumption of the higher protein breakfast decreased appetite (composite of hunger, desire to eat, and prospective food consumption) when compared to skipping breakfast throughout the morning postprandial period. Furthermore, the consumption of breakfast, regardless of macronutrient composition, increased circulating PYY throughout the postprandial period. Baum JI et al. further demonstrated the advantages of a higher protein breakfast by recruiting 16 normal weight and 13 overweight children (10±1y) that habitually skipped breakfast (44). These children were then asked to consume a higher-protein and a higher-carbohydrate ~340 kcal breakfast on two separate days in a randomized order. The consumption of a higher-protein breakfast decreased feelings of hunger, desire to eat, and prospective food consumption and increased feelings of fullness.

A subsequent acute randomized controlled trial conducted in our lab to extend these findings and identify the relative effects of breakfast varying in macronutrient composition on evening ingestive behavior when compared to breakfast skipping (41). In this study, twenty overweight or obese breakfast skipping adolescents were recruited to continue skipping breakfast, consume a breakfast with macronutrients matching a typical American's breakfast, or consume a higher-protein breakfast on three separate days (41). In this study, the consumption of the higherprotein breakfast reduced ghrelin, elevated PYY, and increased fullness compared to a typical breakfast and skipping breakfast (41). Furthermore, the consumption of the higher-protein breakfast increased satiety and reduced evening consumption of high-fat snacks compared to a typical breakfast and skipping breakfast (41). Whereas no differences were observed following the consumption of an isocaloric normal-protein breakfast compared to skipping breakfast (41). Furthermore, the consumption of breakfast, particularly a higher protein breakfast, decreased activation in areas of the brain associated with reward driven eating (41). These reductions were further accompanied by decreased 'unhealthy' evening snacking (i.e. high fat, high-sugar foods) following the consumption of the higher protein breakfasts when compared to a normal protein breakfast and skipping breakfast.

Based on the limited evidence available in children and adolescents, the long-term consumption of breakfast, with nutrition education, may prevent excess weight gain. A growing body of evidence supports the importance of the macronutrient composition of the breakfast, specifically the consumption of higher protein breakfasts, on indices of weight management. Although more long-term randomized controlled trials are necessary, the benefits of a higher protein breakfast may extend to improve overall diet quality.

2.5 Non-school Based Breakfast Interventions and Cognitive Performance

In general, there appears to be a moderate, positive effect for breakfast consumption on subsequent cognitive performance (See Review by Adolphus et al. (16)). Specifically, in tightly controlled, clinical/laboratory environments, breakfast consumption improves attention (6-11), memory (11-13), and executive function (8, 9, 12, 14) compared to when breakfast is skipped. Overall, twenty-five different tasks were used to assess the aforementioned domains. Among those used in more than one study, the Continuous Performance Test (3/4 demonstrated improvements following breakfast consumption), choice reaction time test (1/3), and simple reaction time tests (2/2) were used to assess attention. For memory, free word recalls (2/3), word recognition tasks (2/2), and map tasks (1/2) were most consistently used. Finally, Sternberg Paradigms (2/4), Stroop tests (2/3), and digit span tests (1/3) were used to assess executive function.

Traditionally, the consumption of breakfast was theorized to improve cognitive performance by providing glucose as fuel for the brain (50). In children and adolescents, the consumption of breakfast was considered particularly important because of the increased glucose load required for the developing mind (51, 52). Theoretically, circulating glucose provides energy for central neurons necessary to perform tasks relative to the domains in which observable differences exist. However, glucoregulation, not just overall blood glucose concentrations, may also be a contributor to perceivable differences (53). For example, in a randomized controlled trial of 189 graduate students, an inverse correlation was observed such that lower circulating glucose was associated with more words recalled (54). When stratifying the data according to glucoregulation status, blood glucose was correlated with words recalled for those with adequate glucoregulation but not for those with poor glucose tolerance. Other studies demonstrate similar correlations between glucoregulation and memory (55, 56). However, appropriate methods to trace

biomarkers during cognitive performance assessments are necessary to further breakdown the necessary pathways by which breakfast influences cognitive performance.

In regards to strategies that manipulate the composition of a meal, a number of studies suggest that foods with a lower glycemic load may improve attention (9, 10, 13) and memory (57), and executive function (9). Tasks that demonstrated an advantage of a lower-glycemic load breakfast include a digit vigilance (attention, 1/1), choice reaction time (attention, 1/1), word recognition (memory, 1/1), and a free word recall (memory, 1/3). Although less convincing, there is also evidence that higher glycemic index foods may have an advantage for attention (58), memory (59), and executive function (58). Tasks that demonstrated an advantage of a highglycemic load breakfast include a digit cancellation task (attention, 1/1), Stroop (executive function, 1/1), Serial 7s (executive function, 1/1), and a free word recall (memory, 1/3). Although variance in assessments utilized serve as one explanation for discrepant findings, it has also been previously proposed that glucose and metabolites regulating circulating glucose exert bidirectional effects on subsequent cognitive performance (53). For example, cortisol release following nutrient ingestion and a stress-inducing situation (i.e. testing) may interact at the hippocampus to either encode an event (to avoid later) or inhibit memory formation (53). Although it's unclear as to the effects of breakfast type on cognitive performance, the consumption of breakfast appears to have positive effects on cognitive performance.

To our knowledge, no studies in children and adolescents have examined the effects of breakfasts varying in macronutrient content on subsequent cognitive performance in children or adolescents. In adults, evidence from studies evaluating the macronutrient composition of breakfasts consumed suggests that the consumption of higher protein breakfasts improves memory (immediate word recall and working memory) compared to skipping breakfast, whereas carbohydrates and fats do not (60, 61). However, other studies demonstrate that the consumption of breakfasts composed primarily of carbohydrates improves delayed verbal memory (60) and accuracy (62) compared to isocaloric protein alternatives. Although these results are mixed, the sample size of this body of evidence is limited to three studies in adults. Thus, future research will be useful in identifying consistencies and potential mechanisms by which breakfast improves cognitive performance.

2.6 Barriers to School Breakfast Program Participation

Although increasing evidence supports the daily consumption of breakfast in young people, there must also be efforts to address the issues that deter school-age children from consuming breakfast, particularly at school. In a recent survey conducted by Hearst et al., 832 adolescents from rural high schools in Minnesota were asked what deters their participation in their school's SBP (63). According to those who skipped breakfast three or more days per week, at least 50% of the students indicated that the lack of hunger, time, and taste of breakfast were the primary reasons (63). Others also report a lack of time, skipping breakfast because of weight concerns, and a negative stigma associated with consuming school breakfast as primary reasons (64-67). Addressing these concerns is paramount to the goal of improving SBP participation. If students do not consume the breakfasts, then they may miss the opportunity to experience the benefits. However, the concerns regarding barriers to participating in the SBP are not isolated to the students. Parents also have perceptions that may influence a child's participation in the SBP.

Particularly among the parents of younger students, the negative perceptions of the SBP is a significant barrier in further promoting participation (68). In a survey conducted by Spruance et al., 488 parents of students throughout the state of Utah were asked about their perceptions of school breakfasts and why their children were not participating in the SBP (68). The most commonly cited reasons for why the their children did not participate in the SBP were a result of parents not understanding the need for school breakfasts; a lack of belief that the school breakfasts were healthier than the breakfasts served at home and a belief that the school breakfasts tasted bad, had low nutritional quality, and/or cost too much (68). The aforementioned reasons overlap with the student's perceptions of the SBP. Thus, as schools begin to adapt their SBP to improve participation, they must consider and address the barriers perceived by students and parents.

2.7 School Breakfast Programs

As previously discussed, the requirements set by the USDA for the SBP (**Supplemental Table 1**) are set based on the recommendations set by the Dietary Guidelines for Americans as part of a healthy dietary pattern (24, 69). The prescribed meal pattern for breakfast includes requirements for fruit (or vegetables), whole-grain rich foods and/or meat/meat alternatives, and milk (22, 26, 27, 35). Furthermore, the calorie, sodium, saturated fat, and trans fat content of the meals are restricted based on previous evidence of trends in school breakfast meals (24, 34). Decisions about specific foods served and preparations methods are subject to the local school food authorities and those contracted to make the foods. To track compliance, schools are regularly audited to ensure the meals meet the reimbursable requirements.

Since 1975, approximately 258 million free or reduced breakfasts and approximately 655 million free or reduced lunches have been served to students that qualify for reimbursable meals (19). All students who qualify for a free or reduced breakfast also qualify for a free or reduced lunch. Although the impact of this program is staggering, only 40% of those who qualify for the SBP have participated in it. Although relative participation trends have increased over the years (~57% participation in 2017), strategies are necessary to further improve participation in the

program (25). Thus, recent initiatives have sought to improve the delivery of school breakfasts to address the original intention of the SBP.

2.7.1 School Breakfast Program – Models for School Breakfast Distribution

The recent advent of novel SBPs has provided a number of options for schools to choose from when considering redesigning their schools breakfast program. Second Chance Breakfast, vending machines, and BIC (either Grab & Go or Direct Delivery) are the most widely used, recognized, and reviewed novel programs (70). Each program has benefits and challenges for implementation and maintaining.

The traditional SBP model is set up similar to a traditional school lunch program. Children arrive at the cafeteria, progress through a line, pay for the foods chosen at the end of the line, and then consume the meal in the cafeteria before the first school bell. This long-standing model allows hot foods to be served easily with no special transportation methods to serve the meals. Furthermore, the cafeteria is already set up in such a way the makes provisions for a large number of students to consume their food in one central location. In an effort to summarize teacher perceptions of SBPs, Krueger et. al recently conducted a cross-sectional study to identify the perceived benefits, challenges, and preferences regarding five SBPs (traditional SBP, Second Chance Breakfast, vending machines, Grab & Go Breakfast in the Classroom (BIC), and Direct Delivery BIC) by surveying 369 teachers throughout the state of Utah (71). The SBPs in general were widely supported by the teachers, citing the benefits of breakfast for reduced students' hunger (95%), better academic performance (84%), and fewer behavioral problems (55%) as the most widely anticipated benefits. However, food waste (46%), not enough time for students to eat (34%), and increased supervision needs provided by teachers (31%) were the most widely cited anticipated concerns by the teachers. Of the five SBPs, the traditional SBP was the most approved method of delivery for the school breakfasts at 79%. Better nutrition of the food options available, the improvements on students' academic performance, and the beneficial effect on student's attendance were listed by the teachers as the three most beneficial components of the traditional SBP. In contrast, the increased cleanup required, the greater amounts of food wasted, and the increased of supervision needed were the perceived greatest challenges of the traditional SBP. Thus, programs seeking to improve SBP participation compared to the traditional SBP should seek to address the aforementioned considerations.

Second Chance Breakfast is an alternative breakfast distribution model where students are offered breakfast usually, but not always, after their first period. However, some schools serve breakfast before school and/or in classroom carts in the hallways for students to grab during the morning passing periods. Although the time at which the breakfast is served may change, it is recommended the breakfast is served at least two hours prior to lunch to ensure students have time to eat breakfast when they are hungry in the morning. This method may often accompany the Traditional School Breakfast Model, hence the Second Chance Breakfast name. Alternative names for this model include "Breakfast After First Period," "2nd Chance Breakfast," or "Mid-Morning Nutrition Break." This model is convenient for students and can take less time and/or staff to serve the foods than the Traditional School Breakfast Model. However, it does not provide the same incentive as arriving prior to the first bell for SBPs that serve breakfast before the bell. Furthermore, this program may also disrupt learning via students leaving class to get their breakfast and/or eating breakfasts while the teachers begin their lessons, explaining the lack of approval by the teachers. Specifically, 39.3% of the 369 teachers surveyed by Krueger et al. (71) approved of this method (30.6% had neutral feelings about this program). The greatest anticipated benefits of the 2nd Chance Breakfast method were its potential improvements on students' academic

performance (perceived but not assessed), increased likelihood of students participating, and increased flexibility in how the foods were served. The greatest anticipated challenges by the teachers were the increased cleanup required, the more supervision needed, and the increased time it takes to serve breakfast. Only one study has measured school breakfast participation in a Second Chance Breakfast program compared to a traditional SBP. The study was a cluster randomized controlled trial in forty-three elementary schools with a total of 3,944 fourth and fifth grade students (72) comparing schools utilizing Second Chance Breakfast compared to school utilizing the traditional SBP. Although no difference was observed in the prevalence of students consuming breakfast at schools, the prevalence of students consuming breakfast at home and school (i.e. double breakfasts) was greater in schools utilizing Second Chance Breakfast (15.3%) when compared to schools utilizing a traditional SBP (5.6%). In additional, the 2nd Chance Breakfast schools had fewer students skip breakfast overall (10.4%) when compared to those with a traditional SBP (13.1%).

Vending machines are also sometimes utilized to allow students access to reimbursable breakfast foods. These vending machines are often only available prior to the start of the day and can be set up so that students may request foods using their lunch ID/PIN linked to the schools point of sale system in order to track reimbursable meals. The benefit of this is that students are able to access breakfast without the burden of food service staff or teacher to track participation. This method was approved by 27.6% of the 369 teachers surveyed by Krueger et al. (71) (29.5% had neutral feelings). The greatest anticipated benefits of this method were the decreased time to serve school breakfast, the limited amount of supervision needed, and the potential improvements on students' academic performance (perceived but not assessed). The poor nutrition of food options available, the decreased number of options available, and the increased overall costs

associated with this method were the perceived greatest challenges. To our knowledge, no studies have evaluated the effectiveness of utilizing vending machines to improve SBP participation.

The third novel SBP reviewed, BIC, is a model that serves breakfast to students after the start of the official school day. These breakfasts can be hot or cold items such as breakfast sandwiches, muffins, or cereal, plus a serving of milk and a serving of fruit (to meet the requirements for a reimbursable meal. Breakfast items are delivered from the cafeteria via service carts to kiosks located either in the hallways (Grab and Go method) or directly to the classrooms (Direct Delivery method).

For the Grab and Go method, students take a reimbursable meal from the kiosks and bring the breakfast to the classroom themselves. This method offers an opportunity for higher food quality because the meals can stay at the cart, in a temperature-controlled holding container, until the student picks up the meal. However, for this method, students may have to alter their morning routine to pick up the breakfasts and there may be a greater burden on the teachers to direct the students to the kiosks. This was the second most accepted method (preferred by 53.7%, 13.3% had neutral feelings) by the 369 teachers surveyed by Krueger et al. (71). The greatest anticipated benefits of this method were its potential improvements on students' academic performance, increased likelihood of students participating, and greater flexibility in serving the foods. However, the increased cleanup required, the poor nutrition of the food available, and the increased amounts of food wasted were considered the greatest challenges.

For the Direct Delivery BIC method, the meals are brought right to the classroom from the cafeteria via soft, temperature controlled, coolers for students to pick-up as they come into the classroom. One advantage of this model is that students are not required to do anything besides eat their meal. However, greater responsibility falls on the teacher to distribute individualized meals

to their students and record participation. In addition, some meals are delivered early (i.e. the night before) which may leave them undesirable or completely unpalatable. The time used in the morning for BIC, since it is part of the official school day, is meant to serve as instructional time. This time may also be used for morning announcements, nutrition tips, or traditional lesson plans to use class time to continue teaching material. Direct Deliver was the least acceptable method (58.6% did not approve of this method, 9.5% had neutral feelings) by the 369 teachers surveyed by Krueger et al. (71). The greatest anticipated benefits of this method were the increased likelihood of students participating, the benefits on student academic performance, and increased student attendance (perceived but not assessed). However, the increased time it takes to serve the breakfast, the more cleanup required, and the greater amounts of food wasted were considered the greatest challenges.

Recently, organizations have begun to collaborate to improve SBP participation rates in an effort to combat the previously discussed trends in breakfast skipping. For example, Partners for Breakfast in the Classroom (PBIC), funded by the Walmart Foundation, is a collaboration of the Food Research & Action Center, National Association of Elementary School Principals Foundation, National Education Association Foundation, and School Nutrition Foundation (73). PBIC was established to offer grants to high-need schools to increase breakfast consumption and the associated academic and nutritional advantages after consuming the morning meal (73). The start-up grants from PBIC are provided to schools who can establish that their methods to distribute universally free meals to ALL students are feasible and sustainable without incurring subsequent costs when using a BIC distribution method. This is possible when a significant number of students (i.e. >70%) qualify for free or reduced meals. Thus, the reimbursements from those who qualify for free/reduced meals can offset the costs of meals for students who do not qualify. Overall, in

BIC schools, SBP participation has increased between 30-60 percentage points (74-77). Although studies often fail to delineate whether their BIC model utilize a Grab'n'Go or Direct Delivery model, it is unlikely that differences are observed between these two methods of distributing school breakfast. However, future studies are necessary to affirm such assumptions.

2.8 Weight Management, Diet Quality, and Cognitive Performance in the Context of SBPs

Within the context of school breakfast programs, a paucity of evidence exists elucidating the role of SBPs on weight management. In a cross-sectional evaluation of 2,228 students (grades 1 through 12), Gleason PM et al. observed a decline of 0.15 kg/m² in BMI per day with the implementation of a traditional SBP (78). Further, additional predictive model analyses illustrated that a student who participated every day of the week (5 days) would be expected to have a 0.75 kg/m² lower BMI than the student who does not consume breakfast at all. This would translate to approximately a 1.8 kg reduction in body weight a child who is 2.36 m tall (78). Except for BIC, no studies have examined the effect of alternative SBP model on changes in BMI when compared to the traditional SBP. In regards to the effectiveness of BIC, Corcoran et al used the implementation of BIC in New York City to estimate the program's impact on BMI (75). In this study, changes in BMI in ~720,000 Kindergarten-8th grade students from ~1,000 schools were assessed using a difference-in-difference model. Findings from this study suggest that BIC did not influence BMI nor the prevalence of obesity. However, this study used an intent-to-treat mindset and therefore did not account for students who were actually participating in their school's breakfast program. Furthermore, data from this study was sourced from datasets (New York City Department of Education and its Office of School Food, administrative data gathered from NYC public schools, and measures collected through the city's *Fitnessgram* program) not designed to

assess the effectiveness of BIC. Recently, a more intentional effort was made by Polonsky et al. to assess the effect of overweight and obesity incidence using a cluster-randomized clinical trial design (76). To assess this outcome, Polonsky et al. tracked BMI changes among 1,362 fourth through sixth-grade students (639 attending schools with BIC, 723 attending schools without BIC) from low-income communities over 2.5 years. After 2.5 years, although BIC increased SBP participation, there was no difference between the intervention and control schools in combined incidence of overweight and obesity (11.7 vs 9.3%, respectively). Again, this study did not track individual participation across the 2.5 years. Thus, it appears the program itself does not influence BMI but individual participation in the SBP following the initiation of BIC has yet to be determined.

Although BIC increased SBP participation, the study supporting the aforementioned claims observed students offered BIC were more likely to report eating in two locations (51 vs 30% for the traditional SBP) and consumed 95 kcals more than students not offered BIC (36). These findings led New York lawmakers to halt a statewide implementation of BIC. However, the aforementioned increase in calories following BIC initiation has since been challenged (72). Specifically, to evaluate the effect of SBPs on daily caloric consumption, Ritchie et al. conducted a cluster randomized controlled trial with a total of 3,944 students (72). In this study, trained students participated in a 24-h diary-assisted recall shortly after recording their foods. Findings from this study suggest a trend such that students who attended schools participating in BIC consumed fewer calories over a 24-hour period when compared to students attending schools that utilize a traditional SBP model. The concern of increased calorie consumption has been further refuted by a long-term study conducted by Corcoran et al. using a difference-in difference model to compare changes in BMI within a similar set of New York City schools as Van Wye et al. (75).

Specifically, the findings from Corcoran et al. suggest that BIC does not significant influence BMI as the findings from Van Wye et al. might predict.

However, improving the quality of breakfast served via BIC may be one method to improve students' overall diet quality. In the aforementioned cluster randomized controlled trial by Ritchie et al., students attending BIC schools consumed a higher quality diet, as calculated by the Healthy Eating Index 2010, when compared to students attending schools with either a traditional SBP or Second Chance Breakfast (72). Specifically, these students consumed more fruits and vegetables when compared to their peers attending other schools. Furthermore, manipulating breakfast composition via BIC can also improve the quality of breakfast consumed. In a cross-sectional survey of third, fourth, and fifth grade students in high-need New York City neighborhoods, Van Wye et al. observed students consumed more whole grains via cereal, milk, and fruit juice (requirements for reimbursable meals) for breakfast when attending a school that offered BIC when compared to students attending schools with a traditional SBP (36). In addition, as mentioned within this review, breakfast composition (i.e. a higher protein breakfasts) may be an important factor in reducing unhealthy evening snacking (41). Currently, no studies to our knowledge exists utilizing a BIC intervention to improve overall diet quality. However, as these studies suggest, improving the nutrient density and thus overall quality of the breakfasts served via BIC may be an avenue to improve overall diet quality.

In regard to cognitive performance, a limited number of school-based interventions exist comparing the effects of novel SBPs on subsequent cognitive performance (75, 79, 80). The advantage of school-based interventions is that they more closely align with the participant's normal routine and utilize a more naturalistic breakfast intervention. However, one limitation of many studies attempting to examine the role of novel SBPs, such as BIC, is they often only utilize

grade level data and lack consideration for specific domains. Thus, differences in acute breakfast consumption may mitigate differences that actually exist. In studies assessing the influence of novel SBPs, chronic school breakfast participation resulting from programs such as BIC may improve math and reading achievement scores (79, 80). For example, a difference-in-difference assessment of New York City schools implementing BIC suggests that the novel SBP did not facilitate any improvements in math and reading achievement when compared to schools utilizing a traditional SBP (75). However, in a quasi-random analysis conducted by Imberman SA and Kugler AD, BIC raised math and reading achievement scores by 9% and 6% of a standard deviation when compared to schools utilizing a traditional SBP (80). Similar findings (9% improvements in math and 8% improvements in reading achievement scores in schools participating in BIC) have been subsequently observed using a similar approach (79). However, none of the aforementioned studies controlled time of test administration nor measured acute breakfast consumption, both of which could account for discrepancies.

The lack of clarity elucidating a direct effect of breakfast consumption on relative cognitive performance also serves as a significant barrier in justifying a greater allocation of expenses to novel SBPs. The most common methods of evaluation of the traditional SBP with novel SBPs in the United States are school-wide studies that use group/grade level test scores and SBP participation with intent-to-treat evaluations. Since these evaluations do not track individual performance or participation, there is no way of directly linking participation with test scores. Thus, future studies attempting to elucidate the influence of novel SBPs on subsequent cognitive performance should utilize individual-based outcomes and track day-to-day breakfast consumption.

Although potential mechanisms for acute cognitive performance improvements have been discussed, SBP may improve cognitive performance beyond the aforementioned glucoregulatory mechanisms. For example, providing a nutrient dense breakfast at school may mitigate nutritional deficiencies shown to impair cognitive performance and development. This is particularly important amongst students who are undernourished due to poor diet quality. Deficiencies in various specific vitamins and minerals, including thiamine, vitamin E, and iron, can lead to a decrease in mental concentration and cognition (81, 82). Thus, the SBP may be one independent avenue of providing essential vitamins and macronutrients that are essential for cognitive performance and development, particularly among low socioeconomic (SES) students (34). Because improvements following the consumption of breakfast are regularly observed in studies targeting low SES children/adolescents (i.e. qualify for free/reduced meals) (15, 16), future studies attempting to assess cognitive performance in an ecologically valid environment should target schools participating in a universally free, BIC program. BIC is a particularly useful intervention because of the large breakfast distribution capacity and the high prevalence of low SES students. Potentially hungrier because inadequate morning nutrition, low SES may suffer from preoccupation with food related thoughts, distracting from the task presented during cognitive performance testing. Thus, reductions in hunger or food related thoughts following the consumption of breakfast might serve as one avenue to reduce barriers that hamper performance. Although higher-protein breakfasts increase fullness when compared to lower protein alternatives, it is unclear whether these differences are large enough to facilitate differences in cognitive performance. Thus, future research should seek to whether these differences in satiety influence performance related outcomes, particularly in a school-based environment.

2.9 Future Directions & Considerations

The largest gap in the breakfast literature surrounds the ecological validity (i.e. studies emulating "real-world" environments) of breakfast interventions. This is likely due to a number of difficulties faced when evaluating the appetite, weight, and cognitive performance in school-based settings. Driven by an already set school schedule, the largest obstacle faced may be balancing data collection with appropriate controls (i.e. timing of appetite questionnaires and test administration). Difficulties such as these cause inconsistencies in study designs, one such reason for conflicting findings. Consistent, in depth, standardized procedure would be instrumental in school-based studies. Although some benefits are observed in school-based settings following the consumption of breakfast, further research is necessary to supplement the limited number of studies that exists. When working with schools to maximize SBP participation, it is important to identify the method of distribution for breakfast meals that address the student, parent, and teachers' preferences and weight their preferences with the logistical feasibility of their requests. Furthermore, further research should report the advantages and disadvantages of each novel SBP distribution method to continue to develop more efficient designs. These considerations will mitigate a number of poorly implemented studies.

When considering changes to nutritional quality of the SBP (i.e. the caloric content or the macronutrient distribution of the meal) the economic cost is also a significant consideration. In 2017, approximately \$4.2 billion were provided in federal reimbursements for participation in the school breakfast program (25). Thus, recommendations to consume a breakfast that may even marginally increase the costs (i.e. \$0.10 per meal) may incur larger than anticipated costs (\$250 million) on the federal government, assuming a linear translation of costs. Thus, overwhelming evidence or a recommendation for reallocation of program spending must accompany any legislation facilitating changes to the SBP.

2.10 Summary and Conclusions

The current review summarized the current evidence elucidating the role of breakfast consumption on indices of weight management and cognitive performance with a focus on school breakfast and novel SBPs designed to improve participation in the federal SBP. The findings presented showed a modest support for the consumption of breakfast for indices of weight management and cognitive performance outside of school-based settings. Within school-based settings, a paucity of evidence exists examining the effect of novel SBPs on BMI and cognitive performance. Future studies should target school-based settings to evaluate the effectiveness of novel SBPs on indices of weight management and cognitive performance when compared to a traditional SBP while evaluating the effects of acute and chronic SBP participation at the individual student level.

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2.12 References

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	Brea	Breakfast meal pattern		
	Grades K-5	Grades 6-8	Grades 9-12	
Food Components		Amount of Food a per Week (minimum per day)		
Fruits (cups)	5 (1)	5 (1)	5 (1)	
Grains (oz eq)	7-10(1)	8-10(1)	9-10 (1)	
Fluid milk (cups)	5 (1)	5 (1)	5 (1)	
Min-max calories (kcal)	350-500	400-550	450-600	
Saturated fat (% of total calories)	<10	<10	<10	
Sodium (mg)	≤540	≤600	≤640	
Trans fat	specification	Nutrition label or manufacturer specifications must indicate zero grams of <i>trans</i> fat per serving.		

Supplemental Table 2.1 Meal Requirements for Reimbursable School Breakfast Meals. Adapted from the USDA (28).

Supplemental Table 2.2 The current reimbursement rates (excluding Alaska and Hawaii) for the 2018-2019 school year for students who qualify for free or reduced breakfast and those who do not meet the requirements (paid) (83).

Family Income				
Status	(% of Poverty Level)	Reimbursement Rate ^a		
Free	<130	\$1.79		
Reduced	130 - 185	\$1.49		
Paid	>185	\$0.31		

a. An additional \$0.35 may be provided for each breakfast served in schools where 40% or more of the lunches served during the previous meal were to students who qualify for a free or reduced meal.

CHAPTER 3. HABITUAL BREAKFAST PATTERNS DO NOT INFLUENCE APPETITE AND SATIETY RESPONSES TO NORMAL VS. HIGH-PROTEIN BREAKFASTS IN OVERWEIGHT ADOLESCENTS

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Running title: Breakfast Eating Habits do not Influence Appetite

3.1 Abstract

Objective: The purpose of this study was to examine the effects of habitual breakfast habits on postprandial appetite, satiety, and hormonal responses along with daily food intake following the consumption of Normal-protein (NP) vs. Higher-protein (HP) breakfasts in overweight adolescents. Methods: Thirty-seven girls (age: $19\pm1y$; BMI: 29.0 ± 3.4 kg/m²) participated in the semi-randomized crossover-design study. The participants were grouped according to whether the participants habitually skipped breakfast (SKIP, n=18) or consumed breakfast (CONSUME, n=19). Regardless of group, the participants consumed a NP ((1460-kJ; 13-g protein) or HP (1460-kJ; 13-g protein) or HP (146kJ; 35-g protein) breakfast for 3 days/pattern. On day 4 of each pattern, an 8-h testing day was completed. The respective breakfast was provided and postprandial appetite and satiety questionnaires and blood samples were collected throughout the testing day. Daily food intake was also assessed. Results: No main effects of group (i.e, CONSUME vs. SKIP) were detected for daily hunger, fullness, desire to eat, prospective food consumption, ghrelin, PYY or daily food intake. Regardless of habitual breakfast habits, the consumption of the HP breakfast led to greater fullness throughout the day (29030±6010min*mm) vs. NP breakfast (26910±5580min*mm; p =0.03). In addition, daily protein consumption was greater (98 ± 15 -g vs 78 ± 15 -g) and daily carbohydrate consumption was lower (331±98-g vs 367±94-g) following the HP vs. NP breakfast patterns, respectively (both, p<0.001). No other differences were detected. <u>Conclusion:</u> These data suggest that the recommendation to consume a HP breakfast for improved satiety and ingestive behavior is appropriate for overweight adolescent girls, regardless of habitual breakfast habits.

3.2 Introduction

Childhood and adolescent overweight/obesity remains a global public health crisis. Although the prevalence of obesity in younger children is plateauing, the prevalence of obesity in adolescents continues to increase – with current trends at 20.6%^{1, 2}. In identifying potential behavioral strategies for improvements in obesity-related outcomes in this age group, the daily consumption of breakfast has become one nutrition intervention of interest.

As discussed in several recent reviews^{3, 4}, breakfast consumption, particularly those rich in whole grains, fiber, and/or protein elicit acute improvements in appetite, satiety, and glycemic control compared to skipping the morning meal. Long-term data from our lab also demonstrated long-term improvements in glycemic control, reductions in daily food intake, and the prevention of unhealthy body fat gains following the habitual consumption of higher-protein breakfasts^{5, 6}. However, a number of investigators have proposed that habitual breakfast patterns influence appetitive, metabolic, and weight management outcomes.

Schlundt DG et al. examined the effects of breakfast consumption compared to breakfast skipping and stratified based on habitual breakfast habits. The data, albeit non-significant, suggested that the change in habitual dietary habits (i.e., habitual breakfast consumers beginning to skip breakfast or habitual breakfast skippers beginning to consume breakfast) elicited the greatest effect on weight loss⁷. Along these lines, Thomas EA, et al. and Alwattar AY, et al. reported differences in postprandial insulin, glucose, and/or free fatty acids concentrations that were dependent on habitual breakfast habits^{8, 9}. Lastly, Long SJ, et al. also examined the effects of habitual dietary habits; however, this study examined the effects of habitual protein consumption on satiety. They showed that postprandial satiety was lower following a higher-protein test meal in those who habitually eat a higher-protein diet vs. those that do not¹⁰.

Collectively, these studies support the continued examination of habitual eating habits on obesityrelated outcomes.

Thus, the current study sought to extend the existing evidence to examine the effects of habitual breakfast habits on postprandial appetite, satiety, and hormonal responses along with daily food intake following the consumption of Normal-protein (NP) vs. Higher-protein (HP) breakfasts in overweight adolescents.

3.3 Methods

3.3.1 Experimental Design

Thirty-seven overweight and obese adolescent girls participated in the following randomized crossover-design breakfast study. The participants were grouped according to habitual breakfast habits. Participants were asked to randomly consume either a NP or HP breakfast meal at home for 3 days. On day 4 of each pattern, the participants came to our facilities in the morning to complete the respective 8-h testing day. The respective breakfast was consumed. Pre and postbreakfast appetite and satiety-related blood samples and questionnaires were completed every 30 min throughout the 8-h day. At the end of the testing day, the participants were provided with an ad libitum dinner and evening snack packout, the latter of which was to be consumed at home throughout the evening until going to bed. A 7-day washout period occurred between breakfast patterns.

3.3.2 Study Participants

Between August 2010 and May 2014, adolescent girls were recruited from the Columbia, MO, USA area through advertisements, flyers and email list serves to participate in the study. Eligibility was determined through the following inclusion criteria: (1) age range of 13–20 years; (2) overweight to obese (body mass index: 25-34.9 kg/m2); (3) no metabolic or neurological diseases or other health complications; (4) not been clinically diagnosed with an eating disorder; (5) not currently or previously on a weight loss or other special diet in the past 6 months; (6) documented regular menstrual cycles between 21-36 days in duration for the past 6 months. In addition, a dietary questionnaire was completed to document weekly breakfast habits and/or specific foods consumed. The habitual breakfast skippers (SKIP) consumed breakfast ≤ 2 days/week and the habitual breakfast consumers (CONSUME) at a carbohydrate-rich breakfast (defined as a meal containing 80% of energy as carbohydrates) at least 5 days/week.

Three hundred and fifty teens conveyed interest in participating in the study. Fifty-six met the screening criteria, were available for the 8-h testing days, and began the study. Of these, 37 completed all study procedures (19 SKIP; 18 CONSUME). Demographic data of those who completed the study are shown in **Table 1**. All participants were informed of the study purpose, procedures and risks, and signed the consent/assent forms. The study was approved by the MU Health Sciences institutional review board. The participants received a stipend of \$150/ testing day.

3.3.3 Breakfast Patterns

For 4 consecutive days/pattern, the participants were provided 1460 kJ (350 kcal) NP breakfasts (15% of energy as protein (13 g protein)/65% of energy as carbohydrates/20% of energy as fat) or HP breakfasts (40% of energy as protein (35 g protein)/40% of energy as carbohydrates/20% of energy as fat), in randomized order, to be consumed between 7-9:30 am (prior to school). See Alwattar AY et al. for additional details ⁹.

3.3.4 Specific Testing Procedures on Day 4 of Each Pattern

The participants reported to the research facility between 6 and 9 am after an overnight fast to complete the 8-h testing day. Each participant was seated in a reclining chair and, for the next 30 min, was acclimated to the room and became familiarized with the testing day procedures. A catheter was then inserted into the antecubital vein of the non-dominant arm and kept patient by saline drip throughout the remainder of the testing day. At time – 15 min, a baseline (fasting) blood sample was drawn. At time 0 min, the respective breakfast and 8 oz water were provided during the NP and HP days. The participants consumed the breakfast within 30 min. Postprandial appetite and satiety questionnaires in combination with plasma blood samples were collected throughout the 8-h period. A standard lunch meal was provided 4-h post-breakfast during each testing day. The lunch was 2090 kJ (500 kcal) and contained 15% of energy as protein, 65% of energy as carbohydrates and 20% of energy as fat. At the end of the testing day, the catheter was removed and an ad libitum dinner and evening snack pack-out was provided to the participants as previously described¹¹.

3.3.5 Appetite and Satiety Questionnaires

Computerized questionnaires assessing appetite and satiety were completed prior to consuming breakfast (or the time scheduled to consume breakfast) and every half hour afterwards until leaving the testing facility using a computerized 100 mm visual analog scale. The previously validated questions were worded as "how strong is your feeling of [hunger or fullness]," "how strong is your desire to eat," and "how much food can you eat right now" with anchors of "not at all" or "not much" to "extremely" or "an extreme amount"^{12, 13}. The scores on each question were used to calculate total net incremental area under the curve (AUC) for the perceived appetitive

responses. The Adaptive Visual Analog Scale Software (Neurobehavioral Research Laboratory and Clinic; San Antonio, TX) was used for these assessments.

3.3.6 Repeated Blood Sampling and Hormonal Analyses

Twelve (12) blood samples (4 ml/sample; 76 ml/testing day) were collected throughout each 8-h testing day. Specifically, blood was collected at -15, +0, +30, +45, +60, +90, +120, +150, +180, +210, +240, +270, +285, +300, +330, +360, +390, and +420 min. The samples were collected in test tubes containing ethylenediaminetetraacetic acid. Within 10 min of collection, the samples were centrifuged at -4 °C for 10 min. The plasma was separated and stored in microcentrifuge tubes at -80 °C for future analysis. Plasma active ghrelin and total PYY were measured using the Milliplex MAP magnetic bead-based multianalyte, metabolic panel, 4-plex (Millipore) and Magpix Luminex technologies (Luminex Corporation).

3.3.7 Data and Statistical Analyses

Total net Area Under the Curve (AUC) for hunger, fullness, desire to eat, prospective food consumption, plasma PYY, and plasma ghrelin responses measured throughout each 8-h testing day was determined. Since plasma PYY was not normally distributed, the data was transformed using a natural log function and reported as ln(PYY). Daily energy intake consumed throughout the day was calculated from the standardized breakfast and lunch intake in combination with the ad libitum dinner and snack packout. Boxplots were used to identify and eliminate hormonal outliers, defined as non-physiological concentrations >2SD above/below the mean. Following the elimination of outliers, per-protocol analysis was performed on the remaining individuals.

Mixed factor analysis of variance approach was performed to compare main effects of habitual breakfast habit group (SKIP vs. CONSUME), breakfast patterns (NP meal vs. NP meal), and group x pattern interactions for all study outcomes.

Analyses were conducted using the Statistical Package for the Social Sciences (SPSS; version 21.0; Chicago, IL, USA). P<0.05 was considered statistically significant. All data are reported at mean \pm standard deviation (SD).

3.4 **Results**

3.4.1 Perceived Appetite Responses

Hunger, fullness, desire to eat, and prospective food consumption responses completed every 30 min throughout each of the breakfast patterns along with total AUC responses are shown in **Figures 1 & 2**.

No main effects of habitual breakfast group, breakfast pattern, or group x pattern interactions were detected for hunger (all, p>0.1), desire to eat (all, p>0.05), or prospective food consumption (all, p>0.1), respectively. Although no main effect of habitual breakfast group was detected for daily fullness (p=0.19), the HP breakfast led to greater fullness throughout the testing day (29030 \pm 6010 min*mm) compared to the NP breakfast (226910 \pm 5580 min*mm; p=0.03).

3.4.2 Hormonal Responses

The ghrelin and ln(PYY) responses completed every 30 min throughout each of the breakfast patterns along with total AUC responses are shown in **Figure 3**.

No main effects of habitual breakfast group, breakfast pattern, or group x pattern interactions were detected for ghrelin (all, p>0.1) and ln(PYY) AUC (all, p>0.1).

3.4.3 Energy Intake Responses

Although daily energy was not different between groups or within breakfast patterns, daily protein consumption was greater and daily carbohydrate consumption was lower following the HP vs. NP breakfast patterns (**Table 2**). In addition, a group x pattern interaction was detected for daily fat consumption (p<0.01) such that the consumption of the HP breakfast led to lower daily fat intake vs. NP breakfast within the SKIP participants (p<0.01); this effect was not observed within the CONSUME group.

3.5 Discussion

We sought to examine the effects of habitual breakfast habits and breakfast quality on postprandial appetite, satiety, and food intake in overweight adolescents. Regardless of habitual breakfast habits, the consumption of a HP breakfast increased daily fullness and protein intake while reducing total carbohydrate consumption compared to the NP breakfast. Although habitual breakfast habits had no direct effect on the study outcomes, the reduction in daily fat intake following the HP breakfast pattern was only observed within the habitual SKIP participants. These data suggest that the recommendation to consume a HP breakfast for improved satiety and ingestive behavior is appropriate for overweight adolescents, regardless of habitual breakfast habits.

The universal belief that breakfast is beneficial for health outcomes has recently come under scrutiny due to the limited and inconclusive experimental evidence¹⁴. Although breakfast type and size are critical factors for consideration³, habitual breakfast habits also influence the appetitive and/or metabolic response to breakfast (skipping)⁸. Alwattar et al. reported differences in glucose concentrations that were dependent on habitual breakfast consumption. When compared to those who habitually consumed breakfast, the habitual breakfast skippers experienced greater glucose concentrations throughout the day following the consumption of an HP breakfast vs NP breakfast⁹. Additionally, Thomas EA et al. showed that habitual breakfast consumers elicited greater hunger responses and reduced satiety following breakfast consumption compared to habitual breakfast skippers, regardless whether breakfast was consumed or skipped⁸. Previous evidence from another group suggests that ghrelin concentrations are influenced by habitual meal timing^{15, 16}. Thus, although we expected to observe lower circulating ghrelin within the SKIP vs. CONSUME group, pre and postprandial ghrelin responses were not different. It is possible that the similar ghrelin responses between groups was a result of the inclusion of acclimation days, particularly within the habitual breakfast skippers, which mitigated any habitual hormonal differences^{15, 16}. These findings suggest that the ghrelin response to a dietary intervention, like breakfast, occurs transiently.

Acute feeding trials consistently illustrate increased satiety, as evidenced from postprandial and daily increases in fullness, following the consumption of higher-protein breakfasts, containing 25-30 g protein, compared to the average American breakfast that contains ~15 g protein^{17, 18}. Plasma PYY has been proposed as the gastro-intestinal satiety mechanism since some, but not all studies, illustrate increased PYY concentrations with protein consumption^{11,25}. Although the fullness data within the current study is in agreement with the current body of literature, plasma PYY concentrations in this study were not different. In studies that measure subjective appetite responses in combination with hormonal concentrations, only about 40% detect increases in fullness and increases in circulating PYY following the consumption of higher vs. normal-protein meals¹⁹. Thus, the lack of differences in the current study are not atypical. Traditionally, PYY has been proposed as a potent regulator of satiety²⁰. However, a recent review has challenged this

traditional role, suggesting physiological differences do not necessarily mediate meaningful differences in satiety²¹. The findings in this study support the later view. Future research should continue to elucidate the role this hormone plays in regulating perceived satiety.

The limitations of this study are inherent within the nature of all acute crossover design studies. First, current controversy exists as to whether the acute satiety response following a single HP breakfast translates to reductions in subsequent meal and/or daily food intake. Although some acute studies detect a predictive relationship between perceived appetite and subsequent food intake^{13, 22}, this relationship is inconsistent^{23, 24}. Thus, it is unclear whether changes in perceived daily fullness will alter subsequent meal and/or daily food intake.

In summary, habitual breakfast habits do not influence the majority of appetitive, hormonal, and ingestive behavior responses to HP vs. NP breakfasts. However, the consumption of a HP breakfast increased daily fullness, increased daily protein consumption, and reduced daily carbohydrate consumption compared to the NP breakfast but did not influence 24-h total caloric intake. Collectively, these data suggest that the recommendation to consume a HP breakfast for improved satiety and ingestive behavior is appropriate for overweight adolescent girls, regardless of habitual breakfast habits.

3.6 Conflict of Interest

S. M. D., A. W. B., and H. J. L. have no conflicts of interest.

3.7 Author Contributions

HJL designed the research; SMD conducted research; SMD and AWB analyzed the data, and wrote the first draft of the paper. HJL reviewed and edited the paper. HJL, SMD, and AWB had primary responsibility for the final content. All authors read and approved the final manuscript.

3.8 Funding

The Beef Checkoff and the Egg Nutrition Center/American Egg Board supplied the funds to complete the study.

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	SKIP (n=19)	CONSUME (n=18)
Age (year)	19 ± 1	19 ± 1
Height (cm)	166 ± 5.4	167 ± 7.0
Weight (kg)	80.3 ± 9.9	80.3 ± 9.9
BMI (kg/m^2)	29.0 ± 3.8	28.9 ± 2.9
Frequency of breakfast consumption (no./week)	1 ± 1	6 ± 1
First eating or drinking occasion of the day	$12:30\pm0:15\ pm$	$8:15 \pm 0:10$ am

Table 3.1 Participant characteristics for habitual breakfast skippers (SKIP) and consumers (CONSUME). Data are reported as means \pm SD (when applicable).

Table 3.2 Daily energy content and macronutrient intake following the consumption of a normal-protein breakfast (NP) and a higherprotein breakfast (HP) in habitual breakfast skippers (SKIP) and consumers (CONSUME). Data are reported as means ± SD.

	SI	KIP	CONS	UME	Group Effect	Pattern Effect	Group x Pattern
	NP	HP	NP	HP			
Energy (kJ (kcal))	$\begin{array}{c} 9860 \pm 578 \\ (2360 \pm 138) \end{array}$	9670 ± 552 (2312 \pm 132)	$\begin{array}{c} 10700 \pm 607 \\ (2554 \pm 145) \end{array}$	$\begin{array}{c} 10600 \pm 577 \\ (2542 \pm 138) \end{array}$	0.49	0.22	0.29
Protein (g)	76 ± 4	95 ± 3	79 ± 4	101 ± 3	0.92	< 0.01	0.15
Carbohydrates (g)	346 ± 20	325 ± 21	366 ± 21	343 ± 22	0.71	< 0.01	0.14
Fat (g)	65 ± 5	61 ±5	79 ± 6	79 ± 6	0.12	<0.01	< 0.01



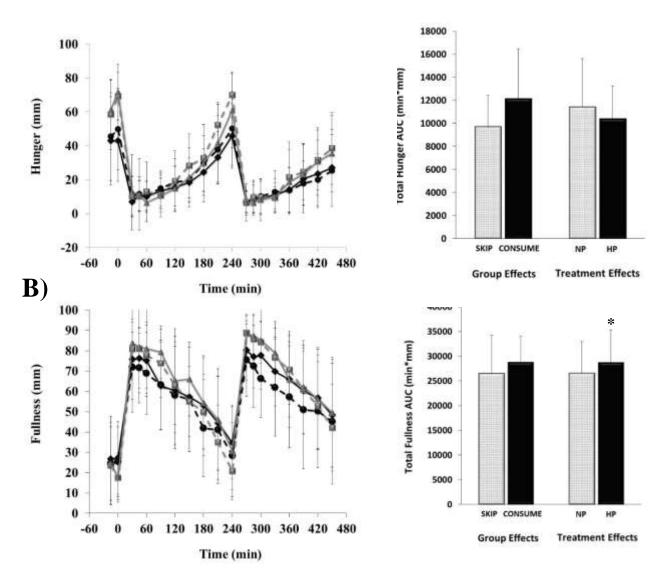


Figure 3.1 Perceived hunger (A) and fullness (B) responses throughout the testing days. The line graph displays the time course of change throughout the 8-h days. * denotes significance between patterns (P < 0.05). Breakfast was consumed at 0 min, and lunch was consumed at 240 min. Data are means ± SD.</p>

SKIP-NP (•), SKIP-HP (•), CONSUME-NP (•), CONSUME-HP (•)

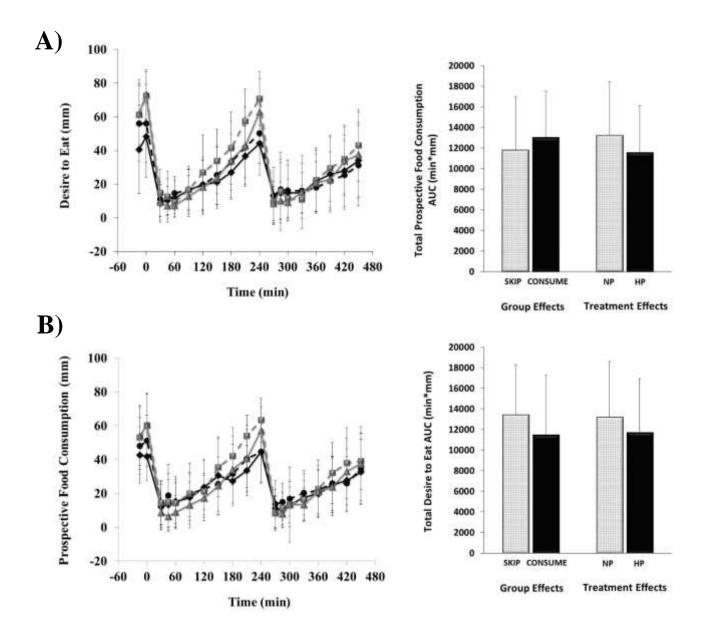


Figure 3.2 Perceived desire to eat (A) and prospective food consumption (B) responses throughout the testing days. The line graph displays the time course of change throughout the 8-h days. * denotes significance between patterns (P < 0.05). Breakfast was consumed at 0 min, and lunch was consumed at 240 min. Data are means ± SD.

SKIP-NP (●), SKIP-HP (♠), CONSUME-NP (■), CONSUME-HP (▲)

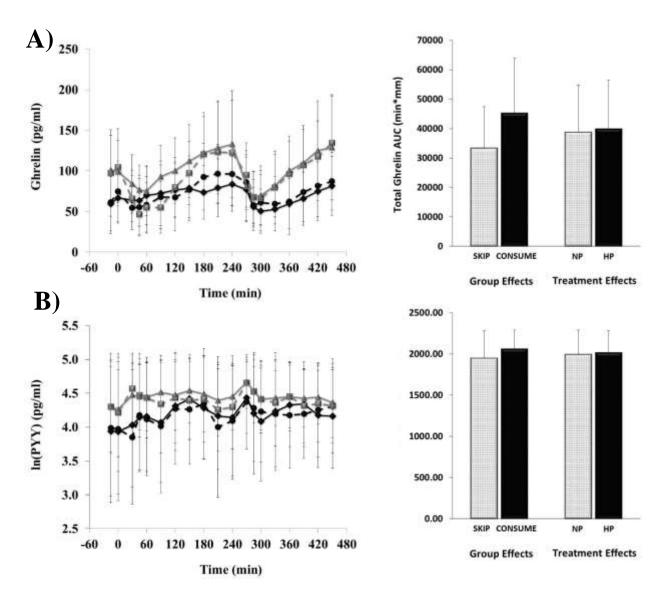


Figure 3.3 Perceived ghrelin (A) and PYY (B) responses throughout the testing days. The line graph displays the time course of change throughout the 8-h days. *denotes significance between patterns (P < 0.05). Breakfast was consumed at 0 min, and lunch was consumed at 240 min. Data are means \pm SD.

SKIP-NP (●), SKIP-HP (♠), CONSUME-NP (■), CONSUME-HP (▲).

CHAPTER 4. A FREE, EGG-BASED 'BREAKFAST IN THE CLASSROOM' PROGRAM IMPROVES SCHOOL BREAKFAST PARTICIPATION AND DIET QUALITY IN MIDDLE-SCHOOL ADOLESCENTS

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Short running head: Egg-based School Breakfast Improves Diet Quality

Abbreviations: BIC, Breakfast in the Classroom; SBP, School Breakfast Program; SSB, sugar sweetened beverages; TSBP, traditional School Breakfast Program

Sources of Support: The American Egg Board supplied the eggs for the study. The remainder of the study was internally funded.

Conflicts of Interest: SMD, MLB, and HJL have no conflicts of interest. MK is a part-time employee of the Center School District (Kansas City, MO).

4.1 Abstract

Background: The increasingly common dietary habit of skipping breakfast has been strongly associated with poor weight management and an increased prevalence of obesity. Recent initiatives have sought improve School Breakfast Program (SBP) participation and the quality of breakfast served at school in order to combat this behavior. Objective: This study examined the effects of implementing a free, egg-based 'Breakfast in the Classroom' program (BIC) on school breakfast participation, breakfast consumption, and snacking behavior compared to a traditional School Breakfast Program (TSBP) in middle-school adolescents within a low socioeconomic school district. Ninety-one, 8th-grade students (age: 14±0.1y; BMI weight-for-age: Methods: 73.1±3.0percentile) participated in the following acute crossover study. School breakfast participation, breakfast consumption at school, and snacking behavior at home were assessed, at baseline, during the TSBP at the Center Middle School, Kansas City, MO. Following these assessments, a 3-wk BIC program was implemented that provided free breakfasts to all 8th grade students using a hallway kiosk system. The BIC breakfasts met all USDA guidelines but included an additional two eggs/day. During week 3 of the BIC program, breakfast and snacking assessments were again completed. Results: BIC led to a 2-fold increase in school breakfast participation (94.4±0.8%) vs. TSBP (37.2±2.9%; P<0.001). Cereal (p<0.03), grains with eggs (p<0.001), eggs alone (p<0.03), and dairy (p<0.01) consumption during school breakfast increased following BIC vs. TSBP. With respect to afternoon/evening snacking behavior, BIC decreased afternoon/evening consumption of salty snacks (P<0.03) and cookies & cakes (P<0.03) at home vs. TSBP. Conclusion: Implementation of a free, egg-based BIC improved school breakfast participation, increased consumption of nutrient-rich foods at breakfast, and reduced unhealthy snacking at home in middle-school adolescents. This trial is registered at clinicaltrials.gov as NCT03536676.

4.2 Keywords

Breakfast in the Classroom, School Breakfast Program, Breakfast, Appetite, Snacking, Food Choice, Protein

4.3 Introduction

The increasingly common dietary habit of skipping breakfast has been strongly associated with poor weight management and an increased prevalence of obesity (1-3). A pivotal study in this area of research included a 5-year prospective analysis of breakfast habits and weight changes in 2,216 adolescents (4). Timlin et al observed that those who skipped breakfast regularly were more likely to gain weight when compared with their breakfast consuming counter parts (4). Additional health and wellness outcomes have also been associated with breakfast skipping including, but not limited to, poor glycemic control (5), reduced satiety (6), lower diet quality (1), and worse cognitive performance in young people (7, 8).

One approach to increase breakfast habits in children and adolescents involves the promotion of the School Breakfast Program (SBP). SBP participation has been associated with reduced obesity rates and improvements in cognitive performance (9-12). However, these results are inconsistent (9, 13, 14), potentially due to the lack of participation in SBPs. Although approximately 14.7 million children and adolescents participate in SBPs (15), that accounts for less than one-fourth of all children and adolescents in the public school systems in the United States (16). Lack of awareness about SBPs; lack of time in the morning upon arriving to school; the perception of poor nutritional/taste quality of the foods; and the social stigma attached with consuming breakfast in the school cafeteria are all reported reasons students choose not to participate in the SBPs (17-21).

In order to improve SBP participation, a number of schools have implemented various programs that offer easier access to breakfast for all students. One such program is 'Breakfast in the Classroom' (BIC), which serves breakfast either at conveniently located school hallway kiosks or directly in the students' classrooms (22, 23). In schools where BIC has been implemented, participation in school breakfast increased between 30 - 60 percentage points (24-27). Although participation in the traditional SBP (TSBP) has been shown to be inversely associated with BMI (28), findings from studies evaluating the effectiveness of BIC on BMI have yet to support these findings (25, 26). However, concerns exist with respect to the quality of breakfast provided within the BIC which may impact the health benefits of these programs.

The current requirements for reimbursable school breakfast include at least 1 cup of fruit, 1 cup of whole-grain rich foods, and 1 cup of milk per day (5 cups of fruit, 7-10 oz equivalents of grains, and 5 cups of milk per week respectively) with no requirements for meat/meat alternatives (29-32). Although meat/meat alternatives may serve as a substitute for half of grain requirements per day, this serves as a sub-optimal amount given the health benefits of increased dietary protein at the breakfast meal (6, 33).

Recent data from tightly-controlled feeding trials in adolescents illustrate increased satiety; reductions in unhealthy snacking behavior; improved glycemic control; and the prevention of unhealthy body fat gain following the daily consumption of higher-protein breakfasts compared to skipping breakfast and/or consuming normal-protein breakfasts (6, 33-36). In examining the types of foods provided within the higher-protein breakfasts within these studies, the majority include eggs as a good source of protein (i.e., scrambled eggs, breakfast burritos, egg sandwiches, etc.) Thus, we sought to extend our lab-based higher-protein breakfast interventions into a school setting.

Thus, this study examined the effects of implementing a free, egg-based 'Breakfast in the Classroom' program (BIC) on school breakfast participation, breakfast consumption, and snacking behavior compared to a traditional SBP (TSBP) in middle-school adolescents.

4.4 Methods

4.4.1 School Setting & Study Participants

The study took place within the Center Middle School in Kansas City, Missouri. The school is an urban district with minority, low-income families. Specifically, 82% of the students are minority (68% black) with 74% eligible for free or reduced school meals, making this an ideal school to promote healthy eating through breakfast consumption.

All eighth-grade students from the Center Middle School in Kansas City, Missouri were invited to participant in the study, which took place during the spring of 2018. Letters were sent home with the students that informed the parents of the study procedures. All students were eligible to participate in the study unless they were wards of the state. One hundred sixty-four students were enrolled in eighth grade and were informed of the study purpose, procedures and risks. Of these, 91 students provided assent and had at least one parent provided consent. Although 91 students began the study, 86 completed all study procedures. The participant characteristics are shown in **Table 1**. The study was approved by the Purdue Biomedical Sciences Institutional Review Board. The participants received a \$25 gift card for completing the study procedures.

4.4.2 Experimental Design

During the baseline week, the school continued the TSBP school-wide. The study participants completed surveys assessing subject characteristics and demographics; school breakfast participation and consumption habits; and snacking habits. In addition, heights were measured using a wall-mounted stadiometer and body weights were assessed using a scale. Following the baseline week, the free, egg-based BIC program was initiated for all 8th grade students, regardless of whether they were in the study; this program continued for 3 weeks. At the end of program, similar surveys as provided during baseline were again completed.

4.4.3 Egg-cellent BIC & Participation

The school set up a 'Grab n' Go' kiosk within the 8th grade wing of the school. All 8th grade students were offered a free breakfast containing fruit, whole-grain-containing foods, and milk based on the USDA requirements for Grades 6-8 (**Table 2**) (37). In an effort to increase the protein content of the school breakfasts, while maintaining the familiarity of the types of foods provided, two whole eggs were incorporated into each meal. The meals were developed by the primary investigator, (H.L.) the school district wellness coordinator (M.K.), and the food service manager (Sodexo; Gaithersburg, MD). Table 2 summarizes the breakfast nutrition information offered to each 8th grade student. Once the students picked up their breakfast, they would take the food into their respective morning classrooms. They had 20 minutes to consume the breakfast.

Participation at baseline (during TBSP) and throughout the BIC program were determined by the electronic school meal tracking system that logs student participation each day for breakfast and lunch.

4.4.4 Breakfast Habits

Breakfast habits were assessed at baseline (during TSBP) and after the BIC intervention using a modified food frequency questionnaire to determine the frequency of breakfast consumption and the types and frequency of breakfast foods consumed (38). The questionnaire includes sixteen commonly consumed breakfast food items. For each food, participants marked how often they consumed the food at home and school, separately, over the past week. The items were then subsequently grouped into the following categories: 1) cereal, 2) fruit (fruit and fruit juice), 3) sausage or bacon alone, 4) grains with eggs (breakfast sandwiches an burritos), 5) grains without eggs (bars, bagels/toast/English muffins, cookies/cakes/donuts, pancakes/waffles/French toast), 6) dairy (milk and yogurt), and 7) eggs alone (scrambled, omelet, hard boiled), and 8) other.

4.4.5 Snacking Habits

Snacking habits were assessed at baseline (during TSBP) and after the BIC intervention using a modified Beverage and Snack Questionnaire (39). The questionnaire included 19 commonly consumed snack foods. For each food, participants marked how often they consumed the food at home over the past week. The foods were then subsequently grouped into the following categories: 1) sugar sweetened beverages (SSB) (orange juice, fruit drinks, sport drinks, flavored water, diet soda, regular soda, energy drinks, and sweetened coffee or tea drinks), 2) dairy (1% or nonfat flavored milk, regular or 2% flavored milk, 1% or nonfat white milk, regular or 2% white milk, low or non-fat frozen desserts, and regular ice cream and milk shakes), 3) salty snacks (low fat chips, regular chips, and generic question asking about other salty snacks), 4) candy, 5) baked desserts/sweets (doughnuts or Poptarts and cookies, brownies, pies, and cakes), 6) vegetables, and 7) fruit.

4.4.6 Data and Statistical Analyses

To quantify the Breakfast Habits survey data, breakfast behaviors were categorized in the following manner. Breakfast skipping was defined as the omission of eating breakfast at home or school ≥ 5 days/week. Frequency of breakfast consumption at school was defined as 'rarely' when

school breakfast was consumed 0-1 time/week; 'infrequent' when breakfast was consumed 2-3 times/week; and 'often' when breakfast was consumed 4-5 times/week.

To quantify the school breakfast participation data, the frequency of breakfast participation within TSBP or BIC was defined as 'rarely' to indicate that the students participated 0-4 times (0-30%) throughout the 3-week assessment; 'infrequent' when the students participated between 5-10 times (31-70%) over the 3-week period; and 'often' when participation occurred >10 times (>70%). In addition, the overall average participation throughout the 3-week periods for the TSBP and BIC were also determined.

All data are reported at mean \pm standard error of the mean (SEM). Paired-sample t-tests were applied to compare the effects of TSBP vs. BIC programs on school breakfast participation, breakfast habits, and snacking habits. Pearson correlations were performed to determine the association between TSBP and markers of weight status. P<0.05 was considered statistically significant. Analyses were conducted using the Statistical Package for the Social Sciences (SPSS; version 24.0; Chicago, IL, USA).

4.5 Results

4.5.1 Breakfast Habits & Participation

Prior to the start of the BIC program, 22.6% of students frequently skipped breakfast. Regarding school breakfast participation at baseline, 42.9% rarely participated in the TSBP breakfast, 31.9% infrequently participated, and 16.5% often participated. As shown in **Figure 1**, overall participation in TSBP was $37.2 \pm 2.9\%$ over the assessment period.

The implementation of the BIC program led to a substantial increase in school breakfast participation. Overall participation in the BIC program was $94.4 \pm 0.8\%$ which was approximately

a 57-percentage point increase from that of the TSBP (Figure 1; p<0.001). When expressed in a different manner, all of the study participants (n=91) participated in the SBP between 4-5 days/wk throughout the intervention, regardless of previous TSBP participation habits. School breakfast consumption was also assessed through a recall questionnaire. Over 50% of the students ate at least half of the school breakfast; 23% of the students ate less than one-fourth of the school breakfast; and 26% ate none of the school breakfast taken from the 'grab and go' bags.

The frequency of breakfast foods consumed by the students was also assessed during the TSBP and BIC through a breakfast food frequency questionnaire. As shown in **Figure 2**, when compared to TSBP, BIC participation increased the consumption of cereal (p<0.03), grain with eggs (p<0.001), eggs alone (p<0.03), and dairy (p<0.01) during breakfast consumed at school. No other differences were detected for the other breakfast items consumed.

4.5.2 Snacking Habits

Afternoon and evening snack habits during the TSBP compared to the BIC are shown in **Figure 3**. The participation in the BIC program decreased the consumption of salty snacks (p<0.03) and cookies and cakes (p<0.03) compared to the TSBP. However, the consumption of sugar sweetened beverages, dairy, candy, vegetables, and fruit consumed as snacks was not different between school breakfast programs.

4.6 Discussion

The implementation of a universally free, egg-based BIC program is feasible and an effective way to improve school breakfast participation compared to the traditional model for school breakfast distribution. Furthermore, the BIC intervention increased breakfast consumption of key, nutrient-dense foods including dairy, whole-grains, and eggs while decreasing afternoon and/or evening snacking on salty and dessert-type foods. Thus, these data suggest that a free, egg-based breakfast is both feasible and likely to improve overall diet quality, via increased nutrient-dense protein-rich foods and reduced 'unhealthy' evening snacking, compared to TSBP in middle school adolescents.

The School Breakfast Program was created in 1966 to improve the nutrition of children and adolescents who may be unable to acquire proper nutrient requirements at home based on their parents' income (40). While the TSBP provides federally subsidized breakfasts to children in need, it continues to evolve to now promote weight management (40, 41). To increase school breakfast participation, the Partners for Breakfast in the Classroom was established to offer support to highneed schools as one strategy to increase breakfast consumption through 'Breakfast in the Classroom' (23).

As discussed earlier, empirical assessments of school breakfast participation following the implementation of BIC strongly support the effectiveness of the novel program. Although design and statistical analyses differ across most BIC studies, the majority illustrate increased participation between 30-60 percentage points in as little as two-weeks after the implementation (24-26). As discussed earlier, the BIC model removes one of the potential barriers of SBP, which is lack of available time for students to eat breakfast at school. Thus, Moeltner et. al completed a 6-week study assessing school participation with several different school breakfast models (27). In the spring, the TSBP was assessed, at baseline for 2-weeks, followed by a 2-week TSBP that included an additional 10 minutes of breakfast time at school. In the fall, BIC was implemented that incorporated the following: 1) classroom setting; 2) additional time to eat breakfast; and a 3) universally free breakfast approach. The addition of 10 minutes in the morning within the TSBP increased school breakfast participation from 37% to 55%, an increase of approximately 18

percentage points. However, the adoption of the BIC improved school breakfast participation to 98.6% which is an increase of approximately 60 percentage points. Furthermore, the percentage of students that report skipping breakfast drops to <1%. The findings from our current study are consistent with the previous study with respect to increased breakfast participation. However, our study sought to extend the findings from previous studies to improve the quality of the breakfast via the addition of eggs.

Along with increased school breakfast participation, BIC may be one method to improve the quality and nutrient density of school breakfast. In a cross-sectional survey of third, fourth, and fifth grade students in high-need New York City neighborhoods, Van Wye et al. conducted a Pearson χ^2 test to estimate the difference in morning food consumption amongst nine schools conducting BIC in some or all of their classrooms versus seven matched schools not conducting BIC (42). In this study, students offered BIC consumed more of the components required for reimbursable meals (whole-gains via cereal, milk, and fruit juice) compared to those schools where BIC was not implemented, demonstrating the influence BIC on breakfast quality. Our interventionbased BIC study supports these findings as the inclusion of an egg-based breakfast served via the BIC distribution model increased the overall consumption of select grains, egg-rich foods, and dairy in the morning meal. Thus, improving the quality of the breakfast served via BIC may be an ideal way to improve the nutrient density consumed at breakfast, potentially influencing overall diet quality.

Previous clinical studies suggest the consumption of breakfast decreases reward driven eating via reduced activation in reward regions of the brain (35). Furthermore, the consumption of a higher-protein breakfast, such as the breakfast provided in the current study, increases satiety and reduces unhealthy evening snacking compared to a typical breakfast and when skipping breakfast (35). The reduction in 'unhealthy' evening snacking (i.e. high fat, high-sugar foods) observed in this study further supports the aforementioned findings and support for increasing protein consumption at breakfast to improve overall diet quality. In an effort to evaluate school-based interventions to promote healthy eating patterns, Ritchie et al conducted a cluster randomized controlled trial in forty-three elementary schools with a total of 3,944 fourth and fifth grade students (43). Following training by the study staff, each of the students participated in a 24-h diary-assisted recall. Students that attended schools participating in BIC reported consuming a higher quality diet, as calculated by the Healthy Eating Index 2010, compared to students attending schools that did not participate in BIC. However, this observation was a result of increased fruit and vegetable intake, not decreased unhealthy evening snacking as observed in our current study. In contrast, Ritchie et al observed an increase in empty calories (i.e. unhealthy evening snacks). Thus, it is possible that higher-protein, egg-based breakfasts, served via a BIC model, might have an added benefit on overall diet quality by reducing empty calories.

One potential barrier with the implementation of a higher-protein breakfast includes the inherent challenges associated with the production and distribution of "hot" meals served via BIC (26). However, we demonstrated high feasibility of distributing higher-protein "hot" meals via BIC. Our current study serves as evidence to refute the misconception that it is not feasible to serve these foods to such a large quantity of students via a 'grab-n-go' BIC program. However, higher food costs, additional staff, storage, and equipment needs must be considered prior to initiation.

Although a number of strengths exist with this study (i.e., the inclusion of a novel, BIC program in a low socioeconomic status middle school with health-focused assessments), a number of limitations exist. The intervention was only 3-weeks in duration; thus, long-term implications

for weight management, health-promotion, and habitual participation cannot be established. Future studies should seek to determine whether the findings from the current study extrapolate to long term changes in body composition and weight management. More importantly, the TSBP was not a universally free system, whereas the BIC program offered free daily breakfasts to all 8th grade students. Thus, we are unable to rule out whether the increased consumption of school breakfast was a result of the type of breakfast provided within BIC (i.e., egg-based breakfast) or simply due to the increased availability of breakfast to all students. Furthermore, when utilizing a 'whole foods' intervention (i.e., 2 eggs/day), we were unable to identify protein-specific effects. Thus, future studies implementing macronutrient-specific breakfasts within a free versus paid system provided through BIC versus TSB programs are needed to isolate potential protein-related breakfast effects on health outcomes.

In summary, implementation of a universally-free, 'Breakfast in the Classroom' containing eggs increased school breakfast participation, improved the quality of breakfast consumed at school, and reduced unhealthy evening snacking in low SES middle school students.

4.7 Acknowledgements

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4.8 Author Contributions

SMD, MLK, and HJL designed the research; SMD, MLK, and HJL conducted research; SMD, MLB, and HJL analyzed the data; SMD wrote the first draft of the paper. All authors reviewed and edited the paper. SMD and HJL have primary responsibility for the final content. All authors read and approved the final manuscript.

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1	
	Mean ± SEM
Sample Size (n)	91
Boys:Girls	42:49
Age (y)	14 ± 1
Height (cm)	166 ± 1
Weight (kg)	66.6 ± 2.0
Hispanic/Latino (%)	18
Racial Minority (%)	82
Black or African American (%)	65.9
American Indians/Alaskan Native (%)	12.9
Other, non-Caucasian (%)	16.5
BMI %ile (age-adjusted)	73.1 ± 3.0
Underweight (<5 th)	3
Normal Weight (5-85 th)	56
Overweight/Obese (>85 th)	41
Socioeconomic Status	
Free/Reduced Meals (%)	60.4

Table 4.1 Participant Characteristics

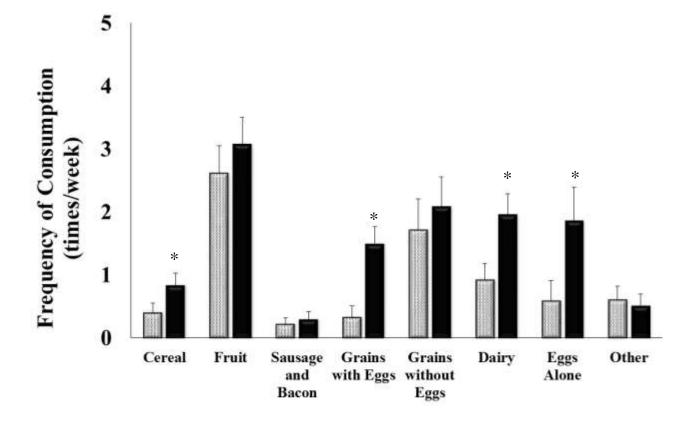
	Traditional	Egg-cellent		
	Breakfast in the Classroom	Breakfast in the Classroom		
USDA Requirements for Reimbursable Meals (37)				
Fruits (cups)				
/wk	5	5		
/day	1	1		
Grains (oz eq)				
/wk	8-10	8-10		
/day	1	1		
Fluid Milk (cups)				
/wk	5	5		
/day	1	1		
Energy (kcal)				
/day	350-500	350-500		
Saturated Fat (% kcal) ^a				
/item	<10	<10		
Sodium (mg)				
/day	<470	<470		
Trans Fat				
/day	0	0		
Nutri	tion Characteristics of Breakfasts (Offered		
95% Confidence Intervals ^b				
Energy (kcal)	(350, 480)	(450, 615)		
Fat (g)	(5, 10)	(15, 25)		
Carbohydrates (g)	(60, 95)	(50, 85)		
Sugars (g)	(35, 60)	(20, 50)		
Protein (g)	(10, 15)	(25, 35)		

Table 4.2 Nutrition Characteristics of Breakfasts

a. Notes requirements for each item, excluding exempt items (i.e. eggs) b. Rounded to the nearest zero or five.

		Egg-cellent
	Traditional	Breakfast in the
	School Breakfast	Classroom
	(TSBP)	(BIC)
Nutrition Characteristics	Per Day	Per Day
Energy Content (kcal)	420	560
Protein (g)	11	24
Fat (g)	5	15
Carbohydrates (g)	83	83
Total Sugar (g)	54	54

Table 4.3 Example Breakfasts Offered within Each School Program



Breakfast Item Categories

Figure 4.1 Frequency of breakfast foods consumed at school with the Traditional School Breakfast Program (TBSP, III) and following the Egg-cellent Breakfast in the Classroom program (BIC, \blacksquare) *TBSP vs. BIC, P < 0.05

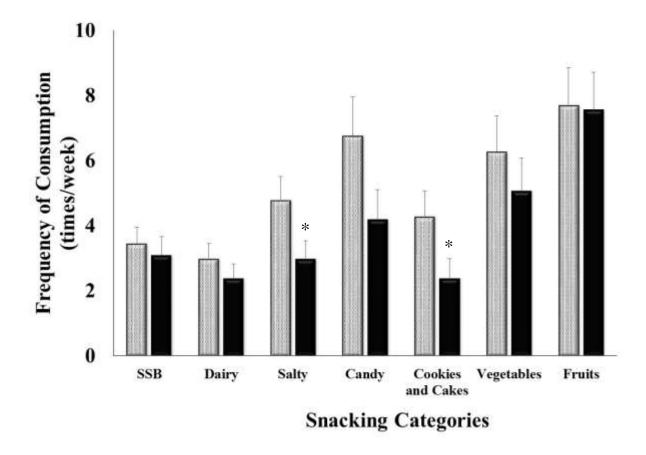


Figure 4.2 Frequency of snack foods consumed at home before (III) and after (\blacksquare) initiation of BIC. *denotes significance following initiation of BIC (P < 0.05). Data are means ± SEM.

CHAPTER 5. STUDENTS WHO PARTICIPATE IN 'BREAKFAST IN THE CLASSROOM' PERFORM BETTER ON TASKS ASSESSING COGNITIVE FLEXIBILITY AND EXECUTIVE FUNCTION

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Short running head: School breakfast improves cognitive performance

Abbreviations: BIC, Breakfast in the Classroom; CNSVS, CNS Vital Signs; FRM, free/reduced meal; HOME, students who consumed breakfast at home only; HP-BIC, high-protein Breakfast in the Classroom; SBP, School Breakfast Program; SCHOOL, students who consumed breakfast at school; SES, socioeconomic status; SKIP, students who skipped breakfast

Sources of Support: The Egg Nutrition Center/American Egg Board supplied the funds to complete the study.

Conflicts of Interest: SMD and HJL have no conflicts of interest. MK is a part-time employee of the Center School District (Kansas City, MO).

5.1 Abstract

Objective: The purpose of this study was to examine the effects of breakfast consumption on midmorning cognitive performance following the implementation of a higher-protein 'Breakfast in the Classroom' program (HP-BIC) in middle-school students. Acute breakfast habits, habitual school breakfast participation, socioeconomic status, appetite, & well-being effects were also assessed. Methods: 764 students in grades 6th-8th participated in the school-wide HP-BIC which offered a free breakfast to every student at the beginning of each school day. The breakfasts met all USDA guidelines with the addition of protein-rich foods, such as eggs. A subset of students (n=278)participated in the following study procedures. During a single day of the HP-BIC, students answered appetite, well-being, and breakfast consumption questionnaires approximately 180 min after school breakfast. Following the questionnaires, a 20-min computerized cognitive performance assessment, CNS Vital Signs, was completed. Students were retrospectively grouped according to breakfast habits on the morning of testing: those who consumed school breakfast (SCHOOL); those who did not consume school breakfast but consumed breakfast at home (HOME); and those who skipped breakfast altogether (SKIP). Results: SCHOOL displayed higher cognitive flexibility (60.0±3.1 percentile-for-age) compared to SKIP (47.2±4.1 percentile-for-age, p<0.05), whereas HOME did not (50.8±4.4 percentile-for age, non-significant). Additionally, SCHOOL displayed higher executive function $(61.2\pm3.1 \text{ percentile-for-age})$ compared to SKIP (48.7 \pm 4.1 percentile-for-age, p<0.05), whereas HOME did not (51.9 \pm 4.4 percentile-for-age, nonsignificant). Habitual school breakfast participation, socioeconomic status, appetite, and wellbeing did not affect cognitive performance. Conclusion: Regardless of behavioral and/or socioeconomic factors, consuming breakfast at school as part of a HP-BIC program, might serve as a strategy to improve select indices of cognitive performance in middle school students.

This analysis was part of a larger trial registered at clinicaltrials.gov as NCT03637010.

5.2 Keywords

Breakfast in the Classroom, School Breakfast Program, Breakfast, Cognitive Function, Cognitive Performance, School-based, Appetite

5.3 Introduction

More than 13 million children live in food insecure homes, many of which arrive to school hungry (1). Since hunger negatively impacts academic performance, behavior, and attention, the promotion of the Federal School Breakfast Program (SBP) may serve as an avenue to curb morning hunger and improve cognitive performance, particularly for students who may not have access to nutrient-dense foods at home (2). In addition, the school breakfast program is designed to include daily fruit, whole-grain, and dairy requirements with the goal to improve diet quality (3).

As demonstrated in a review by Adolphus et al. (4), when students consume breakfast, positive effects on tasks requiring attention, executive function, and memory are observed compared to when students skip breakfast. However, despite these improvements, less than 26% of all students participate in the SBP (5, 6). Thus, initiatives to increase breakfast consumption are warranted.

'Breakfast in the Classroom' (BIC) programs have been developed to improve school breakfast program participation through innovative ways including 'grab and go' breakfast served via hallway breakfast kiosks (7). In our recently completed pilot study, we also modified the types of foods provided within the BIC program to include higher-protein breakfasts (8). The higher-protein BIC program led to a 2-fold increase in school breakfast participation compared to a traditional school breakfast program (p<0.001). The primary source of this protein, eggs, also

serves as a great source for many micronutrients that are often associated with cognitive performance related benefits (9). Although the fat content of eggs exceeds the limits set by the USDA for reimbursable school breakfasts, the beneficial nutrients (i.e. choline, lutein, protein, etc.) and overall nutrient density of the eggs led the USDA to amend previous requirements to allow for the inclusion of eggs (10). Thus, we sought to extend these findings to examine the effects of consuming school breakfast (SCHOOL) following the implementation of a higher-protein 'Breakfast in the Classroom' program (HP-BIC), compared to skipping breakfast (SKIP) or consuming breakfast at home and not at school (HOME), on cognitive performance assessments in middle-school students. Lastly, the potential influence of habitual school breakfast participation, socioeconomic status, appetite, and well-being were also assessed.

5.4 Methods

5.4.1 School Setting & Study Participants

The study took place within the Center Middle School in Kansas City, Missouri. The school is an urban district with minority (82%), low-income families (74% eligible for free or reduced school meals). All students were recruited through letters sent home with the students that informed the parents of the study procedures. All students were eligible to participate in the study unless they were wards of the state. All participants and their parents were informed of the study purpose, procedures, and risks, and signed the consent/assent forms.

Two-hundred seventy-eight middle school students participated in the study procedures. Students were recruited in two cohorts. Fifty-one students were recruited in the first cohort during the Spring 2018 and two-hundred twenty-seven were recruited in the second cohort during the Fall 2018. Baseline characteristics, including body weight and height, were measured using a stadiometer-mounted scale. Age, ethnicity, and habitual breakfast habits were identified through a subject demographic's questionnaire. Lastly, free and reduced meal eligibility (FRM) was documented and used as a proxy for socioeconomic status. Subject characteristics are reported in **Table 1**. The study was approved by the Purdue Biomedical Sciences institutional review board. The participants received a \$25 gift card for completing study procedures.

5.4.2 Experimental Design

All participants were offered the HP-BIC program every morning throughout the study period. The HP-BIC program timeframe varied between cohorts. The Spring cohort received HP-BIC for 3-weeks, whereas the Fall cohort received the HP-BIC for 8-weeks. For both cohorts, breakfast was acquired and consumed upon arrival to school, prior to the beginning of the school day. During a single day of the last week of HP-BIC, students were taken to a quiet, large-group instruction room to complete the 20-min computerized cognitive performance assessment at approximately 180-min after school breakfast. Prior to this assessment, the students answered appetite, well-being, and breakfast consumption questionnaires. Students were subsequently grouped according to breakfast habits on the morning of testing: those who consumed school breakfast (SCHOOL); those who did not consume school breakfast but consumed breakfast at home (HOME); and those who skipped breakfast altogether (SKIP).

5.4.3 BIC Meals & Participation

The school utilized the 'Grab n' Go' hallway kiosk approach within the BIC. All students were offered a free breakfast containing 1 cup of fruit, 1 cup of whole-grain-containing foods, and 1 cup of milk based on the USDA requirements for $6^{\text{th}}-8^{\text{th}}$ grade students (3). Additionally, to increase the protein content of the school breakfasts, protein-rich foods, including 1.5-2 oz

meat/meat alternatives such as eggs, cheese, and/or lean meats were also incorporated into each breakfast. The meals were developed by the primary investigator (H.L.), the school district wellness coordinator (M.K.), and the food service manager (Sodexo; Gaithersburg, MD).

Participation in the BIC program was determined by the electronic school meal tracking system that logs student participation each day for each meal purchased or received.

5.4.4 Breakfast Habits, Appetite, and Well-Being Questionnaires

Paper questionnaires documenting the breakfast habit (i.e., SCHOOL, HOME, SKIP) of each study participant during the morning of the testing day as well as those assessing appetite (hunger, fullness, prospective food consumption) and well-being (energy, sleepy, happy, and stressed) were completed immediately before the cognitive performance assessment (at 180 min post-school breakfast). For the appetite and well-being questionnaires, a 100 mm visual analog scale was utilized. The previously validated questions were worded as "how strong is your feeling of [hunger or fullness]," "how much food can you eat right now," "how much energy do you have," and "How [sleepy, happy, or stressed] are you" with anchors of "not at all" or "not much" to "extremely" or "an extreme amount" (11-13).

5.4.5 Cognitive Performance

Cognitive performance was assessed approximately 180 minutes post-school breakfast using the online CNS Vital Signs neurocognitive assessment system (CNSVS). CNSVS contains a battery of computerized tests to assess various neurocognitive domain states. The battery of tasks used in this assessment included: The Visual Memory, Symbol Digit Coding, Stroop, and Shifting Attention Tests. These specific tasks were designed to generate an output, provided by CNSVS, that summarizes the scores into specific domains (visual memory, reaction time, cognitive flexibility, processing speed, and executive function) based on their performance relative to their same-aged peers. These domains were chosen because of their previously demonstrated sensitivity to breakfast consumption when compared to skipping breakfast in adolescents (4, 14, 15). To account for potential cognitive impairments, participants were excluded if at least one score was less than or equal to the second percentile-for-age (16). In addition, individual invalid results, as noted by the objective CNSVS report, were excluded from analysis.

5.4.6 Data and Statistical Analyses

A series of two-way multivariate analyses of variances (ANOVAs) were performed to compare main effects and interactions of acute breakfast consumption (i.e., SCHOOL, HOME, SKIP); SES status (i.e., FRM eligible vs. FRM ineligible); and habitual BIC participation (i.e., rarely, defined as 0-1 days of participation/week; infrequent, defined as 2-3 days of participation/week; and often, defined as 4-5 days of participation/week) on each cognitive performance domain. When a main effect was observed, between-subject factors were examined within each domain. Independent sample t-tests were conducted to identify differences between groups within each domain where a significant between subject-effect was observed.

In addition, Pearson correlations were performed to determine the associations between appetite, well-being, and cognitive performance outcomes. P<0.05 was considered statistically significant unless otherwise noted. Analyses were conducted using the Statistical Package for the Social Sciences (SPSS; version 24.0; Chicago, IL, USA). All data are reported at mean \pm standard error of the mean (SEM).

5.5 Results

Mid-morning cognitive performance within the breakfast consumption groups are shown in **Figure 1**. A main effect of school breakfast consumption was observed for cognitive performance such that SCHOOL displayed higher cognitive flexibility (60.0 ± 3.1 percentile-forage) compared to SKIP (47.2 ± 4.1 percentile-for-age, p<0.03), whereas HOME did not (50.8 ± 4.4 percentile-for age, non-significant). Additionally, SCHOOL displayed higher executive function (61.2 ± 3.1 percentile-for-age) compared to SKIP (48.7 ± 4.1 percentile-for-age, p<0.03), whereas HOME did not (51.9 ± 4.4 percentile-for-age, non-significant). Cognitive performance based on SES status and habitual school breakfast participation are shown in **Table 3**. No differences in cognitive performance were observed when comparing FRM eligible vs. FRM ineligible students. Lastly, no differences in cognitive performance were detected in those who rarely, infrequently, or often participated in BIC.

Pearson correlation coefficients quantifying the association between cognitive performance within each domain and measures of appetite and well-being are shown in **Table 4.** In addition, no associations were observed between subjective feelings of appetite and well-being and corresponding performance on any of the cognitive domains (p>0.05).

5.6 Discussion

Middle school students who consumed school breakfast as part of a BIC program scored better on tasks assessing cognitive flexibility and executive function when compared to those who skipped breakfast. These higher scores were observed exclusively in those who consumed breakfast at school (not those who consumed breakfast only at home). Key behavioral and/or socioeconomic factors (habitual school breakfast participation, socioeconomic status, appetite, and well-being) did not influence observed cognitive performance. Thus, consuming breakfast at

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school, as part of a HP-BIC program, might serve as a strategy, regardless of the aforementioned factors, to improve select indices of cognitive performance in middle school students.

School-based studies, like this one, that include cognitive performance assessments, often utilize the habitual environment and daily routine of the students, which allows for a greater translation and application of results. Further, because the SBP was originally implemented to improve the nutrition of children and adolescents who may be unable to acquire proper nutrient requirements based on their household income (2), the high prevalence of students qualifying for free/reduced meals in this school further supports the validity of the novel BIC intervention. Thus, the assessment of cognitive performance in this school-based environment provides support for the application of a HP-BIC on cognitive performance, particularly cognitive flexibility and executive function, in a school-based environment. Previous studies that have also implemented BIC have observed improvements in math and reading scores when compared to schools that utilize a traditional SBP (17). Specifically, in a recent quasi-random BIC intervention implemented by Imberman and Kugler (17), a difference-in-differences (a between school change comparison) strategy was utilized to identify differences in math and reading achievement scores when compared with the schools utilizing a traditional SBP. This approach collected achievement scores from 6,353 students in 84 schools over an eleven-week period. Overall, BIC increased math and reading achievement scores (9% and 6% of a standard deviation, respectively) suggesting that BIC is effective for improving achievement scores when compared with a traditional SBP. Although we did not assess achievement scores in the current study, previous evidence suggests cognitive flexibility predicts performance in math and reading scores (18, 19). However, it is unclear whether a HP-BIC intervention, such as the one implemented in the current study, would elicit similar improvements in math and reading achievements scores observed by Imberman and Kugler. Thus,

future studies should seek to compare BIC programs, varying in macronutrient composition, on subsequent testing performance.

Within the context of the current study, it is important to note that those who consumed breakfast at school performed better on the aforementioned cognitive domains when compared to those who skipped breakfast. However, this was not observed for those who consumed breakfast only at home. Although it is unclear why these differences were observed, two theories (breakfast quality and meal timing) may explain such discrepancies.

In regard to breakfast quality, inconclusive data exist assessing the effects of protein quantity on subsequent cognitive performance in children or adolescents. However, the effects of glycemic index/load of a breakfast have been more thoroughly reviewed (4). For example, in a randomized controlled crossover trial conducted by Cooper et al., fifty-two adolescents (12-14 y) were recruited to consume a low glycemic index breakfast, a high glycemic index breakfast, or skip breakfast on three separate days (20). Adolescents responded more accurately on the Stroop, Sternberg, and Flanker tasks following the consumption of a low glycemic index breakfast when compared to a higher glycemic index breakfast and skipping breakfast. Although the aforementioned comparison did not manipulate the macronutrient composition of the meal, it serves as a proof-of-concept that breakfast quality may influence subsequent performance on tasks assessing executive function. Furthermore, previous evidence suggests that participation in a school breakfast program may serve as an avenue to displace a poor quality breakfast at home with a more nutrient dense breakfast at school, particularly among students who qualify for free/reduced meals (21, 22). However, due to timing limitations within the school setting of our current study, we were unable to complete dietary recalls to assess the quality of the breakfasts consumed at home. To examine the acute, causal role of macronutrient manipulation of a breakfast on

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subsequent cognitive performance in adolescents, a randomized controlled crossover should examine differences following the consumption of breakfasts varying in macronutrient composition.

Regarding meal timing, this study administered the cognitive performance tests at a standardized time (i.e., 180 min post-school breakfast) for several reasons (14). Adolphus et al. has shown that mid-morning is the time in which the greatest differences in appetite exists between breakfast consumers and skippers (14). It's possible that the greater delay between eating breakfast at home and the cognitive performance assessment, when compared to the time delay between eating breakfast at school and the assessment, was responsible for the lack of differences observed among those who consumed breakfast at home only. Although the evidence from this study supports Adolphus' observation, additional studies are needed to determine if a time effect following breakfast consumption exists such that decreased cognitive performance is observed because of greater delays between breakfast consumption and task assessment throughout the morning.

Traditional school breakfast participation remains paltry with less than one-third of enrolled students participating and one-half of those who are FRM eligible (5, 6). BIC is one strategy to increase school breakfast participation, particularly for students who qualify for FRM but do not eat breakfast at school due to a number of reasons (i.e. social stigmas, lack of time, etc.). As these students choose to forgo their morning meal, they miss the opportunity to experience the potential benefits of breakfast consumption (23, 24). However, our observations suggest that those who consume breakfast at school perform better on assessments of cognitive flexibility and executive function when compared to their peers who skip breakfast, regardless of FRM eligibility. These differences are not observed when students consume breakfast at home and skip the

breakfast provided at school. Although we expected to observe the greatest benefits for those who qualify for free/reduced meals, the absence of an eligibility interaction supports an overall effect of breakfast consumption at school. Although one purpose of the SBP is to provide meals "to ensure that students enter the classroom well-nourished," in the current study we did not directly assess overall dietary quality or nutrient status (2). Thus, it is possible there were no differences in dietary quality or nutrient status between FRM eligible and ineligible students.

Although a number of strengths exist with this study, the limitations of this study are rooted in the acute, cross-sectional nature of the data collection within the study. Specifically, there is no pre vs. post HP-BIC assessment of change in cognitive performance. Thus, we are unable to elucidate the causal role of acute (or chronic) school breakfast consumption on subsequent cognitive performance. In addition, this study merged the results obtained from two cohorts, varying in the length of the pre-testing treatment period which may have influenced the study findings. However, previous results suggest that differences in math and reading achievement scores within 3-weeks of following an intervention are no different than test scores following 8weeks of initiation. Specifically, in the quasi-random BIC intervention mentioned earlier by Imberman and Kugler (17), BIC increased math and reading achievement scores, regardless of the length of the intervention period. Thus, the length of implementation variation between the cohorts in this study is not likely to serve as a factor in our cognitive performance assessments. Furthermore, habitual school breakfast participation did not influence (directly or via an interaction) subsequent cognitive performance scores, further supporting the unlikeliness that the length of the intervention influenced the observations within this study.

In summary, students who consumed breakfast at school, as part of a HP-BIC program, performed better on tasks assessing cognitive flexibility and executive function when compared with those who skipped breakfast. However, these findings were not observed in those who consumed breakfast at home but not at school. These results were not influenced by FRM eligibility or habitual SBP participation. Furthermore, self-reported appetite and well-being perceptions prior to the cognitive performance assessment were not different between students who consumed and students who did not consume breakfast. Collectively, these data suggest that consuming breakfast at school, as part of a HP-BIC program, might improve select indices of cognitive performance in middle school students, regardless of the aforementioned behavioral and/or socioeconomic factors.

5.7 Acknowledgements

We would like to sincerely thank Linda Williams, Center Middle School Principal, and Dr. Michael Weishaar, Center School District Assistant Superintendent, for their willingness to work with us on implementing this study within the school setting. We would also like to greatly thank Sandy Curran, Center School District Food Service Manager, and her staff, for the collaboration, creativity, hard-work, and time-investment in developing and preparing the breakfast meals for the students.

5.8 Author Contributions

SMD, MLK, and HJL designed the research; SMD, MLK, and HJL conducted research; SMD and HJL analyzed the data; SMD wrote the first draft of the paper. All authors reviewed and edited the paper. SMD and HJL have primary responsibility for the final content. All authors read and approved the final manuscript.

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N	Mean ± SEM
)	278
S	142:136
)	13 ± 0.1
)	156.9 ± 1.7
)	58.3 ± 1.2
<u>n</u>	
)	17.5
)	28.1
)	54.4
)	16
)	77
)	63.7
)	11.4
)	73.0 ± 1.7
)	1
)	55
)	44
<u>s</u>	
)	63

Table 5.1 Participant characteristics. Data are reported as means \pm SEM (when applicable).

	Cohort 1	Cohort 2
USDA Requirem	nents for Reimbursable M	eals (3)
Fruits (cups)		
/wk	5	5
/day	1	1
Grains (oz eq)		
/wk	8-10	8-10
/day	1	1
Fluid Milk (cups)		
/wk	5	5
/day	1	1
Energy (kcal)		
/day	350-500	350-500
Saturated Fat (% kcal) ^a		
/item	<10	<10
Sodium (mg)		
/day	<470	<470
Trans Fat		
/day	0	0
Nutrition Chara	acteristics of Breakfasts O	ffered
95% Confidence Intervals ^b		
Energy (kcal)	(460, 530)	(450, 615)
Fat (g)	(15, 20)	(15, 25)
Carbohydrates (g)	(50, 65)	(50, 85)
Sugars (g)	(25, 40)	(20, 50)
Protein (g)	(25, 30)	(25, 35)

Table 5.2 Nutrition Characteristics of Breakfasts

a. Notes requirements for each item, excluding exempt items (i.e. eggs) b. Rounded to the nearest zero or five.

Table 5.3 Scores on cognitive performance domains for students based on the location of breakfast consumption, free/reduced meal (FRM) eligibility, and habitual School Breakfast Program (SBP) participation. Data are reported as means \pm SEM. Different letters denote significance when main effect exists (p<0.05).

	SES Status			Iabitual School Breakfast Participation		
	FRM	Non-FRM	Rarely	Infrequent	Often	
Visual Memory (%ile for age)	37.9 ± 2.7	42.3 ± 3.7	42.6 ± 5.3	38.7 ± 4.1	39.5 ± 3.1	
Reaction Time (%ile for age)	36.1 ± 2.4	42.7 ± 3.1	40.5 ± 4.2	38.7 ± 3.6	38.4 ± 2.8	
Cognitive Flexibility (%ile for age)	47.8 ± 2.6	56.8 ± 3.4	49.4 ± 5.9	51.5 ± 3.9	52.0 ± 2.7	
Processing Speed (%ile for age)	52.1 ± 2.7	53.2 ± 3.4	58.7 ± 4.6	47.2 ± 4.1	52.7 ± 2.9	
Executive Function (%ile for age)	47.1 ± 2.5	55.8 ± 3.1	48.7 ± 5.2	50.7 ± 3.7	51.2 ± 2.5	

	Hungry	Full	Prospective Food Consumption	Energy	Sleepy	Нарру	Stressed
Visual Memory	-0.08	0.07	-0.09	-0.06	-0.08	0.02	-0.03
(%ile for age)	(0.29)	(0.33)	(0.25)	(0.44)	(0.31)	(0.77)	(0.70)
Reaction Time	-0.10	-0.04	-0.12	-0.02	-0.11	-0.01	0.12
(%ile for age)	(0.23)	(0.60)	(0.13)	(0.84)	(0.16)	(0.91)	(0.12)
Cognitive Flexibility	-0.03	-0.01	0.04	-0.14	-0.10	-0.06	0.13
(%ile for age)	(0.68)	(0.88)	(0.65)	(0.10)	(0.21)	(0.46)	(0.10)
Processing Speed	-0.05	-0.02	0.05	-0.02	-0.01	-0.05	0.10
(%ile for age)	(0.48)	(0.78)	(0.52)	(0.82)	(0.94)	(0.49)	(0.15)
Executive Function	-0.03	0.04	0.06	-0.11	-0.11	-0.04	0.14
(%ile for age)	(0.72)	(0.63)	(0.44)	(0.14)	(0.15)	(0.63)	(0.07)

Table 5.4 Pearson correlations (with p-values in parentheses) between performance on each cognitive domains and perceived appetite and well-being. * denotes p<0.05 Prospective

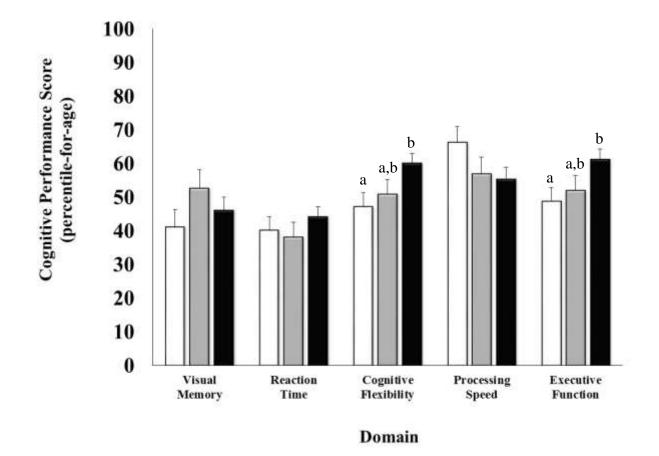


Figure 5.1 Cognitive Performance scores for students who skipped breakfast (□), who consumed breakfast at home only (□), and who consumed breakfast at school (□) the morning of the evaluation. Different letters denote significance when main effect was observed (p < 0.017, when adjusted for multiple comparisons). Data are means ± SEM.

CHAPTER 6. CONCLUSIONS AND FUTURE DIRECTIONS

6.1 Major Findings & Summary

The current dissertation examined the feasibility of implementing a higher-protein breakfast in a school-based setting and the effect of a higher protein breakfast on appetite, hormones, eating behavior, and cognitive performance.

The studies included within this dissertation examined the effects of dietary protein at breakfast on appetite, eating behavior, and cognitive performance. The findings of these studies suggest: 1) the consumption of a higher-protein breakfast for improved satiety is appropriate for overweight adolescent girls, regardless of breakfast habits; 2) implementing a free, higher-protein, egg-based 'Breakfast in the Classroom' program is feasible and improved school breakfast participation, increased consumption of nutrient-rich foods at breakfast, and reduced unhealthy snacking at home in middle-school students; and 3) Students who consumed breakfast at school, as part of a 'Breakfast in the Classroom' program, performed better on tasks assessing cognitive flexibility and executive function when compared to students who skipped breakfast, regardless of key behavioral and/or socioeconomic factors.

- **6.1.1** *Increased dietary protein consumed in the morning:* Increased daily fullness, daily protein consumption, and reduced daily carbohydrate consumption compared to a normal protein breakfast but did not influence 24-h total caloric intake.
 - Did not influence perceived appetite and ingestive behavior related hormones differently in overweight habitual breakfast consuming teenage girls when compared to their breakfast skipping peers.

6.1.2 In a school-based environment, the implementation of a universally free, higher protein 'Breakfast in the Classroom' containing eggs:

- Was feasible in a middle school setting and increased school breakfast participation.
- Improved the quality of breakfast consumed at school and reduced unhealthy evening snacking in eighth grade students.

6.1.3 Students who consumed breakfast at school, as part of a universally free, 'Breakfast in the Classroom' program:

- Performed better on tasks assessing cognitive flexibility and executive function when compared to their breakfast skipping peers.
- Did not perform any better than students who consumed breakfast at home. However, no differences in performance were observed between students who consumed breakfast at home and students who skipped breakfast.

6.2 Study Limitations & Future Directions

To conclude this dissertation, we will review select limitations, discuss future directions, and consider improved designs for future studies. Given the differences in design and breadth of considerations within each study, we will address each individually within the context of the overall findings.

The first study of this dissertation (Chapter 3) sought to examine the effects of habitual breakfast habits on postprandial appetite, satiety, and hormonal responses along with daily food intake following the consumption of normal-protein vs. higher-protein breakfasts in overweight adolescents. As adolescent overweight/obesity remains a public health concern, identifying behavioral strategies, such as the daily consumption of breakfast, for improvements in obesity-

related outcomes has become a pertinent goal among those seeking to curb the ongoing epidemic. In this study, the consumption of a higher-protein breakfast improved fullness and increased protein intake when compared with a normal protein breakfast, regardless of habitual breakfast consumption. However, the limitations within this study design, as such is the case within all crossover design studies, limit the long-term implication of the aforementioned study conclusions. In particular, it is unclear how changes in perceived fullness translate to long-term changes in weight. The variability in the predictive relationship between perceived appetite and subsequent food intake has caused some to question the ecological validity of long-term inferences. Thus, future studies must seek to determine whether the acute improvements in fullness following the consumption of a higher protein when compared to a normal protein breakfast in habitual breakfast consumers extrapolate to long-term improvements in indices of weight management. The results from the study discussed in Chapter 3 suggests that there are no short-term differences between habitual breakfast skippers and habitual breakfast consumers following the consumption of a higher-protein breakfast when compared to a normal protein breakfast. Although a previous study from our lab suggests long-term benefits in fat mass change following the consumption of breakfast when intervening in habitual breakfast skippers (1), a similar study in habitual breakfast consumers is necessary to see if the results from our current study extend to similar long-term findings. Furthermore, the feasibility of long-term changes in macronutrient manipulation (i.e. consuming a higher-protein breakfast) is a concern. Specifically, the increased demands on time of preparation, the costs, and lack of availability of protein-rich foods may deter long-term adherence to such a diet. Thus, the second study of this dissertation sought to address these concerns by providing a higher-protein breakfast in a school-based setting.

The second study of this dissertation (Chapter 4) sought to examine the feasibility and relative effects of implementing a free, higher-protein, egg-based 'Breakfast in the Classroom' program on school breakfast participation, breakfast consumption, and snacking behavior compared to the traditional School Breakfast Program in middle-school adolescents within a low socioeconomic school district. Since the initiation of the School Breakfast Program, the objectives have been to improve the nutrition of children and adolescents who, because of financial reasons, may be unable to consume a well-balanced diet (2). This study was the first of its kind to implement and affirm the feasibility of a higher-protein 'Breakfast in the Classroom' program within a schoolbased setting. However, the acute nature of this pilot study limits the long-term implications of such an intervention. Specifically, the 3-week duration of this study prevents long-term conclusions that extrapolate the improvements in breakfast quality and the reduction in unhealthy evening snacking observed in this study to overall health benefits. Furthermore, the lack of a control comparison (i.e. a Breakfast in the Classroom program that serves a traditional school breakfast) prevents conclusions about the role of breakfast quality on the aforementioned benefits. Therefore, we are unable to rule out whether the changes observed were caused by a universally free breakfast available to all students. Future studies should seek to compare a higher-protein Breakfast in the Classroom program with a Breakfast in the Classroom program that serves a traditional school breakfast on breakfast consumption (i.e. quantity and quality) and evening snacking; and whether programs differing in breakfast composition facilitate changes in weight, waist circumference, and/or body composition. Finally, this study was not a randomized controlled trial. This is primarily because of the limitations within a school-based setting and the pilot nature of this study. Future studies should be designed as randomized controlled trials in multiple schools,

that randomize the schools and the order schools receive (for a cross-over design) Breakfast in the Classroom with/without a higher-protein breakfast.

The final study of this dissertation (Chapter 5) sought to examine differences in cognitive performance between 6th-8th grade students who consume school breakfast, students who consume breakfast at home only, and students who skip breakfast following a higher-protein Breakfast in the Classroom program with consideration for the potential influence of habitual school breakfast participation, socioeconomic status, appetite, & well-being. The necessity for studies such as this is driven by the large number of children living in food insecure homes, often being deprived of their morning meal and arriving to school hungry (3). This morning hunger impairs students' ability to learn. Although programs are in place to provide breakfast to these students at school, a number of deterrents prevent them from doing so (4-7). The largest limitation of this studies design is inherent within its observational design. Specifically, the lack of pre-post breakfast and pre-post intervention assessments prevent causal conclusions about the effects of breakfast and/or the intervention itself. Furthermore, as discussed within the context of the previous study, the students in this study consumed a higher protein breakfast as part of a school-wide Breakfast in the Classroom program. The breakfast consumed at home was not assessed and therefore no inferences can be made regarding the role of breakfast quality on subsequent cognitive performance. Studies implementing a randomized controlled trial with multiple schools that randomize the schools who receive Breakfast in the Classroom and the order they receive Breakfast in the Classroom with/without a higher protein breakfast should also assess changes in cognitive performance within the context of each intervention (i.e. traditional School Breakfast Program, higher protein Breakfast in the Classroom, and Breakfast in the Classroom that serves a traditional school breakfast). Finally, the cognitive performance assessments in this study were collected from two

cohorts varying in intervention period length. Although previous evidence suggests this limitation does not influence changes in math and reading achievement scores (8), it is unclear whether these differences influence the domains assessed in this study. Although no differences between cohorts were observed in this study, future research is necessary to determine direct implications of varying acclimation periods.

6.3 References

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APPENDIX A. COGNITIVE PERFORMANCE OUTPUT FILE (EXAMPLE)

CNS Vital Signs Report Test Da				Date: December 11, 2018 09:33:25					
				Administrator:					
Age: 13 Language: Eng					English (I	United States	s)		
Total Test Time: 14:31 (min:secs) CNSVS Duration: 14:26 (min:secs)			s)	Online Ver	rsion 1.1.0				
Patient Profile	Percentile				>74	25 - 74	9-24	2 - 8	<2
Patient Prome	Standard	Standard Score Range			> 109	90 - 109	80 - 89	70 - 79	< 70
Domain Scores	Patient Score	Standard Score	Percentile	Valid Score**	Above	Average	Low Average	Low	Very Low
Visual Memory	45	94	34	Yes	-	X	1.000		
Reaction Time*	632	109	73	No		X			
Cognitive Flexibility	-26	52	1	No					X
Processing Speed	29	75	5	Yes			1	X	
Executive Function	-3	70	2	No				X	

Domain Dashboard: Above average domain scores indicate a standard score (SS) greater than 109 or a Percentile Rank (PR) greater than 74, indicating a high functioning test subject. Average is a SS 90-109 or PR 25-74, indicating normal function. Low Average is a SS 80-89 or PR 9-24 indicating a slight deficit or impairment. Below Average is a SS 70-79 or PR 2-8, indicating a moderate level of deficit or impairment. Very Low is a SS less than 70 or a PR less than 2, indicating a deficit and impairment. Reaction times are in milliseconds. An * denotes that "lower is better", otherwise higher scores are better. Patient Scores are raw scores calculations generated from data values of the individual subtests.

VI** - Validity Indicator: Denotes a guideline for representing the possibility of an invalid test or domain score. "No" means a clinician should evaluate whether or not the test subject understood the test, put forth their best effort, or has a clinical condition requiring further evaluation.

Visual Memory Test (VSM)	Score	Standard	Percentile	
Correct Hits - Immediate	12	92	30	Visual Memory test: Subjects have to remember 15 geometric figures, and recognize them in a field of 15 distractors. The test is repeated at
Correct Passes - Immediate	13	111	77	the end of the battery. The VIM test measures how well a subject can
Correct Hits - Delay	7	- 71	3	recognize, remember, and retrieve geometric figures e.g. exploit or attend symbolic or spatial representations. "Correct Hits" refers to the
Correct Passes - Delay	13	110	75	number of target figures recognized. Low scores indicate visual memory impairment.
Symbol Digit Coding (SDC)	Score	Standard	Percentile	
Correct Responses	31	76	5	The SDC test measures speed of processing and draw upon several cognitive processes simultaneously, such as visual scanning, visual
Errors*	2	93	32	perception, visual memory, and motor functions. Errors may be due to impulsive responding, misperception, or confusion.
Stroop Test (ST)	Score	Standard	Percentile	Possibly Invalid
Simple Reaction Time*	191	118	88	The ST measures simple and complex reaction time, inhibition /
Complex Reaction Time Correct*	638	100	50	disinhibition, mental flexibility or directed attention. The ST helps assess how well a subject is able to adapt to rapidly changing and
Stroop Reaction Time Correct*	626	114	82	increasingly complex set of directions. Prolonged reaction times
Stroop Commission Errors*	23	-7	1	indicate cognitive slowing / impairment. Errors may be due to impulsive responding, misperception, or confusion.
Shifting Attention Test (SAT)	Score	Standard	Percentile	Possibly Invalid
Correct Responses	38	89	23	The SAT measures executive function or how well a subject recognizes set shifting (mental flexibility) and abstraction (rules.
Errors*	41	58	1	categories) and manages multiple tasks simultaneously. Subjects have to adjust their responses to randomly changing rules. The best scores are high correct responses, few errors and a short reaction
Correct Reaction Time*	442	144	99	time. Normal subjects may be slow but accurate, or fast but not so accurate. Attention deficit may be apparent.

APPENDIX B. DETERMINATION OF VALID COGNITIVE PERFORMANCE ASSESSMENT

		Validity Criteria
Visual memory	Raw score on the Visual Memory task is greater than 30	Visual Memory Test is valid
Reaction Time	Simple reaction time is less than complex reaction time which is less than Stroop reaction time on the Stroop Test	Stroop Test is valid
Cognitive Flexibility	The number of correct responses is greater than the number of incorrect responses on both the Shifting Attention Test and the Stroop Test.	Shifting Attention Test and Stroop Test are valid
Processing Speed	The number of correct responses on the Symbol Digit Coding test is at least 20 and the number of correct responses is greater than the number of errors committed	Symbol Digit Coding Test is valid
Executive Function The number of correct responses on the shifting attention test are greater than the number of errors committed		Shifting Attention is valid

Source: www.cnsvs.com

APPENDIX C. EVALUATION OF EACH DOMAIN BASED ON INDIVIDUAL TASK PERFORMANCE

Clinical Domains	Domain Score Calculations
Visual momory	Visual Memory Test Correct Hits Immediate + Visual Memory Test Correct Passes Immediate
Visual memory	+ Visual Memory Test Correct Hits Delay + Visual Memory Test Correct Passes Delay
Reaction Time	(Stroop Test Complex Reaction Time Correct + Stroop Reaction Time Correct)/2
Cognitive Flexibility	Shifting Attention Test Correct Responses – Shifting Attention Test Errors – Stroop Commission Errors
Processing Speed	Symbol Digit Coding Correct Responses – Symbol Digit Coding Errors
Executive Function	Shifting Attention Test Correct Responses – Shifting Attention Test Errors

Source: www.cnsvs.com

APPENDIX D. CHAPTER 3 CONSENT FORMS

STUDY CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

INVESTIGATOR'S NAME: HEATHER J. LEIDY PROJECT #: 1173258

FOR HS IRB USE ONLY	
APPROVED	
\sim	
	8/27/10
HS IRBAuthorized Representative	
HS ING AUTIONZED Representative	Date
EXPIRATION DATE: 8-27-20)//

STUDY TITLE: THE BENEFICIAL EFFECTS OF DIFFERENT BREAKFAST MEALS ON APPETITE CONTROL & COGNITION IN 'BREAKFAST SKIPPING' YOUNG WOMEN

INTRODUCTION

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

This is a research study. Research studies include only people who choose to participate. As a study participant/parent of a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is simply an effort to make you better informed so that you may give or withhold your consent to participate/allow your daughter to participate in this research study.

Please take your time to make your decision and discuss it with your family and friends.

You/your daughter are being asked to take part in this study because you/your daughter follow the potentially unhealthy habit of skipping breakfast.

This study is being sponsored by the American Egg Board/Egg Nutrition Center and the National Cattlemen's Beef Association.

In order to participate in this study, it will be necessary to give your written consent.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to identify how the body and mind respond to the daily consumption of different breakfast meals in 'breakfast skipping' young women.

This research is being done because we currently do not know why breakfast is widely assumed to be "the most important meal of the day."

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 25 people will take part in this study at the University of Missouri, Columbia, MO.

WHAT IS INVOLVED IN THE STUDY?

If you/your daughter take(s) part in this study, there will be 3 different breakfast patterns to complete in any order. These include skipping breakfast or eating our "Rise & Shine" breakfast meals.

Each breakfast pattern will be followed for 7 days each. For the 'Breakfast Skipping' pattern, breakfast will be skipped as normal. However, for the other patterns, we will provide different types of meals to consume at home between 6-8 am for 6 days for each pattern.

Each breakfast meal will be prepared in a separate container and marked as Breakfast Day 1-6. Each morning, you/your daughter will read the breakfast meal instruction sheet. This sheet includes the directions for preparing each breakfast meal, a check-off log listing all of the foods to be consumed, and several short questionnaires regarding you/your daughter's feelings, thoughts, and mood towards the breakfast meal. You/your daughter will be permitted to only eat the foods provided by the study. However, after breakfast is completed, you/your daughter can eat or drink anything else you/your daughter chooses to eat throughout the remainder of the day. All of the breakfast meals consist of normal breakfast foods commonly consumed by those who eat breakfast on a daily basis. The next page lists the description of the breakfast meals.

Breakfast Menus

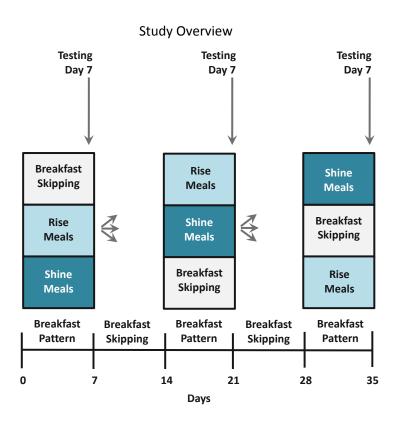
Rise Breal	kfast Meals	Shine Breakfast Meals		
Cheerios-style Cereal with Milk (Days 1,3,5,7)	Flake-style Cereal with Milk (Days 2,4, 6)	Waffles, Syrup, & Sausage (Days 1,3,5,7)	Breakfast Wrap (Days 2, 4, 6)	
<u>Cereal includes</u> : 1 cup Cheerios® 1 cup Multi-grain Cheerios®	<u>Cereal includes</u> : 1 cup Rice Krispies® ¹ / ₄ cup Special K Protein ^{+®} ³ / ₄ cup Grapenuts Flakes®	Waffle Batter includes: 1 oz Powdered Milk 5 g Vital Wheat Gluten ¹ / ₃ Piece of Lavash Bread 1 ¹ / ₂ Tbsp Benefiber® ¹ / ₂ Tbsp Margarine ¹ / ₂ cup Liquid Egg Whites	Sandwich ³ ⁄ ₄ Piece of Lavash Bread 2 oz Lean Ground Beef 1 ¹ / ₂ cup Liquid Egg Whites 1 ¹ / ₈ oz Skim Milk ³ / ₄ slice American Cheese ¹ / ₃ Tbsp Benefiber®	
<u>Milk includes</u> : 5 ¹ / ₂ oz Vitamin D Milk 2 oz Skim Milk	1 Tbsp Benefiber® <u>Milk includes</u> : 6 ¹ / ₂ oz Vitamin D Milk 1 oz Skim Milk	Syrup 1 ¹ / ₂ tsp Maple Syrup 1 ¹ / ₃ oz Sugar Free Maple Syrup <u>Beef Sausage</u> 2 oz Lean Ground Beef 1 g of Sausage Spice	<u>Yogurt</u> 3 oz French Vanilla Yogurt	

On day 7 of each pattern (which will be on Saturdays), you/your daughter will report to the Melvin H. Marx Building on the MU campus to complete the 12-h testing day.

Here are the procedures that will be completed during thus day:

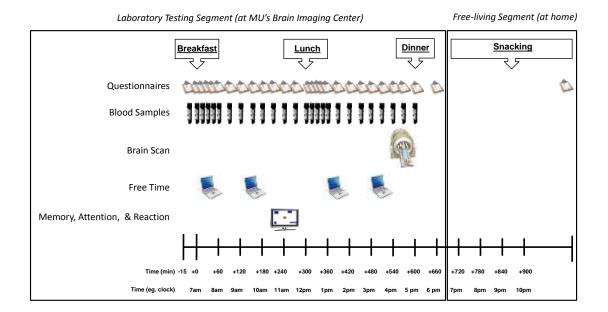
- Upon arriving, you/your daughter will have your/your daughter's body weight measured and will then sit in a comfortable, reclining chair. All of the testing procedures will be explained one more time.
- When ready to begin, a catheter, which is a thin flexible, plastic tube, will be inserted into a vein located in the front (inside) of the elbow by a registered nurse or trained research technician using sterile techniques. The vein will be kept patent (i.e. 'cleared' or 'flushed') throughout the day by using a slow continuous dripping of sterile saline solution. We use the catheter so that we can take multiple blood samples without having to stick you/your daughter multiple times.
- A small blood sample (~ 1 teaspoon) will be drawn from the catheter. The blood sample will be used to measure hormones, which are chemical messengers in the body, that respond to food intake. Also at that time, a questionnaire will be completed which asks about your hunger feelings, thoughts of food, and mood.
- Throughout the day, blood samples and questionnaires will be collected at specific times.

- We will provide breakfast, lunch, and dinner at specific times. These will include common foods that young people typically eat on a daily basis.
- Right before lunch, a "Memory, Attention, & Reaction" test will be completed on the computer. This will take approximately 45 minutes.
- Right before dinner, the catheter will be removed and a brain scan will be completed using a brain imaging method known as Magnetic Resonance Imaging (MRI). This technique examines how water molecules in the brain behave in a strong magnetic field. MRI provides a detailed picture of what the brain looks like. We also use the functional MRI technique which provides information on blood flow and 'brain activation.' This is a non-radioactive (i.e., no x-rays), non-invasive technique. During this scan, you/your daughter will lie on a table that 'slides' into the scanner. Your/your daughter's head will be set in a specific testing position-making it difficult for you/your daughter to move your/your daughter's head. During the scan, you/your daughter will view numerous food, animal, scenery, and blurry pictures. You/your daughter will be asked to remember the pictures that you/your daughter saw during the scanning. This procedure lasts approximately 30 minutes.
- Throughout the day (when you/your daughter are not completing the testing procedures), you will have 'free time' to do the following things:
 - We will provide a laptop to play a number of "Hidden Objects/Seek and Find" computer games or check email, Facebook, etc.
 - We will provide a DVD player with movies to choose from.
 - We will also provide various card and board games to play.
 - You/your daughter can also bring magazines and/or books to read.
 - You/your daughter will be permitted to use the restrooms in the facility at any time.
- At the end of the day, we will provide a pack-out cooler containing numerous snacks to freely consume, at home, throughout the remainder of the evening.
- Over the next 7 days, you/your daughter will go back to your normal pattern of 'Skipping Breakfast.' Sometime during this week, you/your daughter will return the pack-out cooler to us. At that time, we will provide the next breakfast pattern to you/your daughter.
- You/your daughter will repeat these procedures for each of the 3 breakfast patterns.
- Each breakfast pattern lasts for 7 days. There is a 7-day 'Breakfast Skipping' pattern in between each one of these. Thus, the entire study lasts a total of 35 days (i.e., 5 weeks).
- We have performed similar studies in this age group and have found that most young people easily tolerate and actually enjoy each part of the study.



Here are 2 diagrams of the entire study and the specific 12-hour testing day:

12-hour Testing Day



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HOW LONG WILL I/MY DAUGHTER BE IN THE STUDY?

We think you will be in the study for 35 day (i.e., 5 weeks).

The investigator may decide to take you/your daughter off this study if new medication is prescribed by your/your daughter's doctor that would alter the study outcomes or if you/your daughter are not correctly following the breakfast patterns.

You can stop participating at any time. Your/your daughter's decision to withdraw from the study will not affect in any way your medical care and/or benefits.

However, if you/your daughter decide(s) to withdraw from the study, we ask that all study forms and supplies be returned to our facility in a timely manner.

WHAT ARE THE RISKS OF THE STUDY?

While in the study, you are at risk for the side effects described below. You should discuss these with the investigator and/or your/your daughter's doctor. There may also be other side effects that we cannot predict. Many side effects go away shortly after each testing day is completed, but in some cases side effects can be serious or long-lasting or permanent.

Risks and side effects related to the study breakfast meals include:

Unlikely; with some Short-term Discomfort; Otherwise not Serious:

Your/your daughter's stomach and/or bowels may become slightly upset due to the changes in your/your daughter's usual food and beverage intake. Any discomfort should stop within 1-2 days.

Risks and side effects related to the blood collection procedures include:

Likely; with some Short-term Discomfort

There may be some risks when having a catheter inserted into your/your daughter's arm. During the insertion, some pain may be felt which feels like a slight pinch. The pain will end within seconds after the insertion is completed.

There is a risk of developing a small bruise and/or infection. However, the catheter will be inserted by a highly trained nurse or technician using sterile techniques.

You/your daughter may feel lightheaded and may faint at the sight of blood. Neither of these will occur due to the amount of blood being drawn. In fact, throughout each testing day, we will collect approximately 125 ml (4.2 oz)/testing day; this is about 26% of what would be taken if you/your daughter donated blood through the American Red Cross. Thus, the amount of blood collected is small enough not to present any hazard to you/your daughter's physical wellbeing. However, you/your daughter must agree not to donate blood for at least one month prior to, during, and for one month after the study.

There are no substantial risks associated with this procedure.

Risks and side effects related to the brain scan (MRI) procedures include:

Less Likely; with some Short-term Discomfort

Although MR imaging is thought to be hazard free, you may feel physically uncomfortable or anxious

when placed in the enclosed space of the MRI device. This is the same size space of the 'mock' scanner that you/your daughter laid down in during the screening meeting. You will be able to talk to a staff member by using a microphone and speaker system.

Noise from the MRI machine can also cause discomfort. Earplugs and/or earphones are provided to minimize this discomfort.

Reproductive Risks

The effects of the MRI procedures on a developing fetus (unborn baby) are unknown but could cause harm. For this reason, if you are pregnant or could become pregnant, then you must not participant in this study.

There are no substantial risks associated with this procedure.

For the reasons stated above the investigator will observe you/your daughter closely while giving the treatment described and, if you/your daughter have any worrisome symptoms or symptoms that the investigator or *her* associates have described, notify the investigator immediately. The *Investigator's* telephone number is 573-882-0654. For more information about risks and side effects, please feel free to ask the investigator.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. You may expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge. We hope the information learned from this study will benefit other 'breakfast skipping' individuals in the future.

You/your daughter may experience benefits from this study by understanding why your/your daughter's current dietary habits are unhealthy and potentially lead to reward-driven eating, increased motivation to eat, and overeating. This study will further show you/your daughter which dietary strategies might be the most beneficial in order to reduce these unhealthy and unwanted behaviors.

There is no guarantee that taking part in this research will result in any improvement in your/your daughter's eating habits.

WHAT OTHER OPTIONS ARE THERE?

An alternative is to not participate in this research study.

WHAT ABOUT CONFIDENTIALITY?

Information produced by this study will be stored in the investigator's file and identified by a code number only. The code key connecting your/your daughter's name to specific information about you/your daughter will be kept in a separate, secure location. Information contained in your/your daughter's records may not be given to anyone unaffiliated with the study in a form that could identify you/your daughter without your written consent, except as required by law. If the investigator conducting this study is not your/your daughter's primary, or regular doctor, she must obtain your permission before contacting your/your daughter's regular doctor for information about your/your daughter's past medical history or to inform them that you/your daughter are in this study.

It is possible that your/your daughter's medical and/or research record, including sensitive information and/or identifying information, may be inspected and/or copied by the Food and Drug Administration (FDA), federal or state government agencies, or hospital accrediting agencies, in the course of carrying out their duties. If your/your daughter's record is inspected or copied by any of these agencies, the University of Missouri will use reasonable efforts to protect you/your daughter's privacy and the confidentiality of your/your daughter's medical information.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your/your daughter's name or other identifying information will not be used in any publication or teaching materials.

In addition, if photographs are taken during the study that could identify you/your daughter, you/your daughter must give special written permission for their use. In that case, you/your daughter will be given the opportunity to view the photographs before you give permission for their use if you/your daughter so request.

WHAT ARE THE COSTS?

There is no cost to you for the breakfast meals, dietary information, blood analyses, and the brain scan images of your/your daughter's brain that are all part of this research study. Parking is also free of charge at the Brain Imaging Center parking facility. The only cost you/your daughter will have is the cost with traveling to and from the University of Missouri.

WILL I/MY DAUGHTER BE PAID FOR PARTICIPATING IN THE STUDY?

You/your daughter will be compensated a total of **\$450** for completing all study procedures. Specifically, you/your daughter will be paid \$150 for completing each breakfast pattern which includes the 12-hour testing day and the 6 days of correctly following the specific breakfast pattern at home.

WHAT IF I/MY DAUGHTER AM INJURED?

It is not the policy of the University of Missouri to compensate human participants in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to

participants who suffer injuries while participating in the research projects of the University of Missouri. In the event you/your daughter have suffered injury as the result of participation in this research program, you/your daughter are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

WHAT ARE MY/MY DAUGHTER'S RIGHTS AS A PARTICIPANT/PARENT OF A PARTICIPANT?

Participation in this study is voluntary. You/your daughter do not have to participate in this study. Your/your daughter's present or future care will not be affected should you/your daughter choose not to participate. If you/your daughter decide to participate, you/your daughter can change your/your daughter's mind and drop out of the study at any time without affecting your/your daughter's present or future care in the institution. Leaving the study will not result in any penalty or loss of benefits to which you/your daughter are entitled. In addition, the investigator of this study may decide to end your/your daughter's participation in this study at any time after she has explained the reasons for doing so and has helped arrange for your/your daughter's continued care by your/your daughter's own doctor, if needed.

You will be informed of any significant new findings discovered during the course of this study that might influence your/your daughter's health, welfare, or willingness to continue participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you/your daughter have any questions regarding your/your daughter's rights as a participant in this research and/or concerns about the study, or if you/your daughter feel under any pressure to enroll or to continue to participate in this study, you/your daughter may contact the University of Missouri Health Sciences Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-3181.

You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact Heather J. Leidy, primary investigator, at 573-882-0654.

A copy of this consent form will be given to you to keep.

SIGNATURE

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as potential benefits that I/my daughter may experience have been explained to me. Alternatives to my/my daughter's participation in the study also have been discussed. I have read this consent form and my questions have been answered. My signature below indicates my willingness to participate/allow my daughter to participate in this study.

Participant (if ≥ 18 yrs of age)	Date	
Participant-Assent to Participant (if between the ages of 15-17 yrs)	Date	
Legal Guardian/Advocate/Parent	Date	
Additional Signature (if required); Identify relationship to Participant	Date	

SIGNATURE OF STUDY REPRESENTATIVE

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered questions regarding the study to the best of my ability.

Date

Study Representative

BLOOD BANKING

Lagree to allow the use of my/my daughter's blood samples collected during this study to be used for future research that might be unrelated to this study. The blood samples will be stored for 10 years. These samples will likely be used for future analysis of food intake and appetite hormones that have not yet been identified or are currently unable to be measured. The use and disclosures of personal information listed in the consent form also apply to the saved blood samples. However, at any time, I can request that the blood samples be destroyed if I change my mind. If this occurs, I will provide a written request to Dr. Leidy at 204 Gwynn Hall; University of Missouri; Columbia, MO 65211. Lastly, I understand that Dr. Leidy can use and share information that was gathered before this request was received.

Participant (if ≥ 18 yrs of age)	Date
Participant-Assent to Participant (if between the ages of 15-17 yrs)	Date
Legal Guardian/Advocate/Parent	Date
OR	
I request my /my daughter's blood samples collected during this stu future research that is unrelated to this study. I understand that I/r participate in this study if I refuse to have the blood samples retained	ny daughter can still

Participant (if ≥ 18 yrs of age)	Date	
Participant-Assent to Participant (if between the ages of 15-17 yrs)	Date	
Legal Guardian/Advocate/Parent	Date	

STUDY CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

INVESTIGATOR'S NAME: HEATHER J. LEIDY PROJECT #: 1204820

Study Title: Power-up with Protein

INTRODUCTION

This consent may contain words that you do not understand. Please ask the Investigator or the study staff to explain any words or information that you do not clearly understand.

Note: If you are the parent of a potential participant (between the ages of 16 and 17 years), please be aware that the language in the consent is directly written for the study participant. Thus, we use 'you' and 'yours' to describe the procedures that the study participant will be completing.

This is a research study. Research studies include only people who choose to participate. As a study participant, you have the right to know about the procedures that will be used in this research study so you can make the decision whether or not to participate. The information presented here is simply an effort to make you better informed so that you may give or withhold your consent to participate in this research study.

Please take your time to make your decision and discuss it with your family and friends.

You are being asked to take part in this study because you are a young people who regularly eat carbohydrate-rich breakfast and lunch meals.

This study is being sponsored by the Egg Nutrition Center/American Egg Board and National Cattlemen's Beef Association.

In order to participate in this study, it will be necessary to give your written consent/assent.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to identify how the body and mind respond to the daily consumption of breakfast and lunch meals differing in normal and higher protein foods.

This research is being done because we currently do not know how the body and mind respond to specific combinations of normal vs. higher protein breakfast and lunch meals.

HOW MANY PEOPLE WILL TAKE PART IN THE ACTUAL STUDY?

About 25 people will take part in the actual study at the University of Missouri, Columbia, MO.

WHAT IS INVOLVED IN THE STUDY?

If you decide to take part in this study, there will be 4 different meal patterns to complete in any order. All of these meals include breakfast and lunch.

Each meal pattern will be followed for 4 days. For all patterns, we will provide different types of breakfast and lunch meals to consume at home. You will be expected to eat the breakfast meals between 6-9 am and the lunch meals between 10 am-1 pm for 3 days for each pattern.

Each meal will be prepared in a separate container and labeled as Pattern #, Breakfast Day 1-3 or Lunch Day 1-3. Each day, you will read the breakfast meal and lunch meal instruction sheets. These sheets include the directions for preparing each meal, a check-off log listing all of the foods to be consumed, and several short questionnaires regarding your feelings, thoughts, and mood towards the meal. You will be permitted to only eat the foods provided by the study for breakfast and lunch. However, after breakfast **and** lunch are completed, you can eat or drink anything else you choose to eat throughout the remainder of the day. All of the meals consist of normal foods commonly consumed by those who eat breakfast and lunch on a daily basis.

On Day 3 of each pattern, you will be given a dinner meal to eat between 3-6 pm. Once you eat this meal at the designated time, you will be expected to not eat or drink anything else until breakfast at our facility the next morning.

On Day 4 of each pattern, you will report to either McKee Gym Rm 10 on the MU Campus or the Clinical Research Center located on the 5th school of the School of Medicine on the MU Campus to complete the 10-hour testing days.

Here are the procedures that will be completed during each 10-hour testing day:

- Upon arriving, you will have your body weight measured and will then sit in a comfortable, reclining chair. All of the testing procedures will be explained one more time.
- You will be given an activity monitor to wear throughout the testing day. The monitor is a small device that looks like a pager, which measures your activity levels while you wear it. You will keep this on the entire day and will continue to wear it when you go home.
- When you are ready to begin the testing day, a catheter, which is a thin flexible, plastic tube, will be inserted into a vein located in the front (inside) of the elbow by one of the highly-trained research staff members using sterile techniques. The vein will be kept patent (i.e. 'cleared' or 'flushed') throughout the day by using a slow continuous dripping of sterile saline solution. We use the catheter so that we can take multiple blood samples without having to stick you multiple times.
- A small blood sample (~ 1 teaspoon) will be drawn from the catheter. The blood sample will be used to measure hormones (chemical messengers in the body) that respond to food intake.

Also at that time, a questionnaire will be completed which asks about your hunger feelings, thoughts of food, and mood.

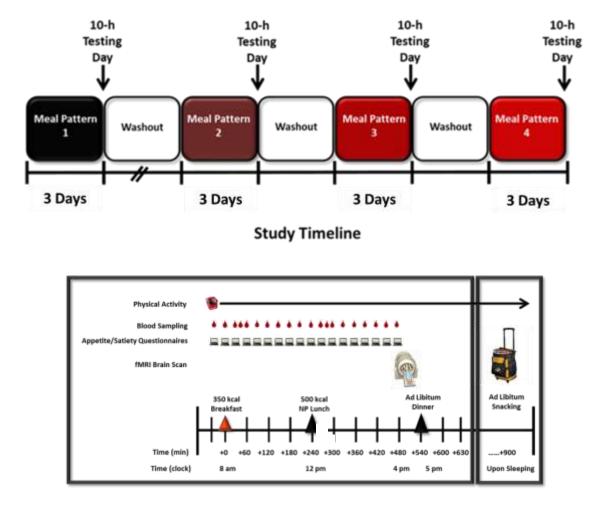
- We will provide breakfast, lunch and dinner at specific times. These will include common foods that young people typically eat on a daily basis.
- Right before dinner, the catheter will be removed and a brain scan will be completed using a brain imaging method known as Magnetic Resonance Imaging (MRI). This technique examines how water molecules in the brain behave in a strong magnetic field. MRI provides a detailed picture of what the brain looks like. We also use the functional MRI technique which provides information on blood flow and "brain activation." This is a non-radioactive (i.e., no x-rays), non-invasive technique. During this scan, you will lie on a table that "slides" into the scanner. Your head will be set in a specific testing position making it difficult for you to move your head. During the scan, you will view numerous food, animal, scenery, and blurry pictures. This procedure lasts approximately 30 minutes.
- Throughout the day (when you are not completing the testing procedures), you will have "free time" to do the following things:
 - We will provide a laptop to play a number of "Hidden Objects/Seek and Find" computer games or check email, Facebook, etc.
 - We will provide a DVD player with movies to choose from.
 - You can bring magazines and/or books to read.
 - You will be permitted to use the restrooms in the facility at any time.
- At the end of the testing day we will provide a pack-out cooler containing numerous snacks to freely consume throughout the remainder of the evening.

You will repeat these procedures for each of the next 3 meal patterns.

Each meal pattern lasts for 4 days (i.e., 3 acclimation days and 1 testing day/pattern). There will be a washout period in between each pattern. During this time, you will simply return to your normal breakfast and lunch meals. The washout periods can be a short as 7 days or as long as 3 weeks, depending on holidays, schedules, etc.

We have performed similar studies in this age group and have found that most young people easily tolerate and actually enjoy each part of the study.

The diagrams below show the entire study overview and the specific 10-hour testing day procedures:



HOW LONG WILL I BE IN THE STUDY?

You will be completing 4 meal patterns which are 4 days/pattern in duration. Thus, the study procedures last for a total of 16 days. However, due to the washout periods in between the meal patterns, you will be enrolled in the study between 7 weeks and 16 weeks.

The Investigator may decide to take you off this study if new medication is prescribed by your doctor that would alter the study outcomes or if you are not correctly following the meal patterns.

You can stop participating at any time. Your decision to withdraw from the study will not affect in any way your medical care and/or benefits.

However, if you decide to withdraw from the study, we ask that all study forms and supplies be returned to our facility in a timely manner.

WHAT ARE THE RISKS OF THE STUDY?

While in the study, you are at risk for the side effects described below. You should discuss these with the Investigator and/or your doctor. There may also be other side effects that we cannot predict. Many side effects go away shortly after each testing day is completed, but in some cases side effects can be serious or long-lasting or permanent.

Risks and side effects related to the study meals include:

Unlikely; with some Short-term Discomfort; Otherwise not Serious:

Your stomach and/or bowels may become slightly upset due to the changes in your usual food and beverage intake. Any discomfort should stop within 1-2 days.

Risks and side effects related to the blood collection procedures include:

Likely; with some Short-term Discomfort

There may be some risks when having a catheter inserted into your arm. During the insertion, some pain may be felt which feels like a slight pinch. The pain will end within seconds after the insertion is completed.

There is a risk of developing a small bruise and/or infection at the catheter site. However, the catheter will be inserted by a highly trained technician or registered nurse using sterile techniques.

You may feel lightheaded and may faint at the sight of blood. Neither of these will occur due to the amount of blood being drawn. In fact, throughout each testing day, we will collect approximately 80 ml (2.7 oz.)/testing day; this is about 17% (for each testing day) of what would be taken if you donated blood through the American Red Cross. Thus, the amount of blood collected is small enough not to present any hazard to your physical well-being. However, you must agree not to donate blood for at least one month prior to, during, and for one month after the study.

There is a risk of developing a small rash or rash-like symptoms including redness, bumps and itching as a result of the adhesive used to secure the catheter and IV tubing to the arm during the testing day. This irritation generally clears up within 2 hours after removing the adhesive.

There are no substantial risks associated with this procedure.

Risks and side effects related to the brain scan (MRI) procedures include:

Less Likely; with some Short-term Discomfort

Unlike x-rays or CT-scans, MRI does not involve any ionizing radiation. However, the tasks may cause some fatigue similar to reading a book or doing homework. You may also experience discomfort from lying still. If this happens, please let us know and we will arrange for you to adjust your position. Additionally:

The safety of MRI has been evaluated over the past 20 years and no short-term effects have been observed. However, the long-term effects of MRI on the body are not fully known. Some individuals with claustrophobia (fear of closed or confining spaces) may find the MRI equipment too confining. In that case, you can request to be removed from the scanner and this will be done immediately. If you have any concerns about this, you can be placed in a MRI simulator to determine if the confining aspects and noises are too uncomfortable.

The MRI scanner makes sounds variously described as "thumping", "pounding", "banging", "chirping" and "buzzing"; these sounds can be loud. You will be required to wear protective earplugs and headphones during scanning to reduce the noise. However, you will be able to hear the Technologist and he/she can hear your voice when you respond.

The Investigators for this research project are not Licensed or Trained Diagnosticians or Clinicians. The testing performed in this project is not intended to find abnormalities, and the images or data collected do not comprise a diagnostic or clinical study. The Investigators and the University of Missouri are not responsible for failing to find abnormalities. However, on occasion the Investigators may perceive possible abnormalities. When this occurs, the Brain Imaging Center will consult with a Specialist. If the Specialist determines that additional inquiry is warranted, a staff person from the Brain Imaging Center will contact you. In such case, you are advised to consult with a Licensed Physician to determine whether further examination or treatment would be prudent. The Investigators, Specialist, Brain Imaging Center and the University of Missouri are not responsible for any decision you make with regard to examination or treatment. Because the images collected for this research project do not comprise a diagnostic or clinical study, the images will not be made available for diagnostic or clinical purposes.

No short-term effects to a fetus from this procedure have been observed. However, the long-term effects of MRI on the fetus are not fully known. Therefore, if you are sexually active and capable of becoming pregnant, you must use an effective method of birth control while participating in this research. If you are a subject in a multi-session study and become pregnant during the course of that study, you will no longer be able to participate in this MRI research study for the duration of your pregnancy.

You cannot have an MRI if you have any metal in or near your brain such as an aneurysm clip or a cochlear implant, or other contra-indicated implants such as a pacemaker for your heart or metalcontaining prostheses (like a 'stent' or a heart valve, hearing aids, etc.). For example, welders and metal workers may be at risk for a MRI because they may have gotten small metal fragments in their eyes. This would be dangerous inside the magnet. There are also possible risks for participants if metal objects are drawn to the magnet while a participant is within or near the bore. Accordingly, you will be asked to leave all jewelry and metal objects outside of the testing area. No loose metal objects will be allowed near the magnet. Many items of clothing contain metal hooks, wires, etc. and some of these cannot be worn in the MRI device. We have clean garments that you can wear in this case.

For the reasons stated above the Investigator will observe you closely while giving the treatment described and, if you have any worrisome symptoms or symptoms that the Investigator or her associates have described, notify the Investigator immediately. The Investigator's telephone number

is 573-882-0654. For more information about risks and side effects, please feel free to ask the Investigator.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

The need for healthy eating is an important part of everyone's lifestyle. With increasing concerns of obesity and other health related factors with food consumption, it is important to gain understanding in the quality of food that we consume on a daily basis. By examining different eating patterns, we are able to gain a better understanding surrounding the control of appetite and food intake regulation.

The knowledge gained from the results of this study will benefit society by providing insights as to whether a modest dietary strategy containing increased dietary protein at breakfast and/or lunch might lead to beneficial alterations in appetite control and subsequent food intake for better weight management.

You may individually experience benefits from this study by understanding the differences between different meal types and the associated effects on appetite control, food reward/cravings, and unhealthy snacking.

Great care will be taken in the planning and execution of this study to help ensure the safety and well-being of each participant. The risks associated with participation are no more than a minor increase over minimal risk; the potential gains for the participant, as well as society as a whole, are great. We believe this research is very important to combat adolescent obesity. Safe and effective ways to control body weight are important to prevent or delay the onset of complications from obesity, such as diabetes and heart disease. Overall, we believe this research protocol presents a very good risk-benefit ratio. Further, we are confident that this study will provide meaningful and useful information to aid in the development of recommendations to better manage energy balance and hopefully curb the increasing prevalence of abnormal weight regulation.

WHAT OTHER OPTIONS ARE THERE?

An alternative is to not participate in this research study.

WHAT ABOUT CONFIDENTIALITY?

Information produced by this study will be stored in the Investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law. If the Investigator conducting this study is not your primary or regular doctor, she must obtain your permission before contacting your regular doctor for information about your past medical history or to inform them that you are in this study.

It is possible that your medical and/or research record, including sensitive information and/or identifying information, may be inspected and/or copied by the Food and Drug Administration (FDA), federal or state government agencies, or hospital accrediting agencies, in the course of carrying out their duties. If your record is inspected or copied by any of these agencies, the

University of Missouri will use reasonable efforts to protect your privacy and the confidentiality of your medical information.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials.

In addition, if photographs are taken during the study that could identify you, you must give special written permission for their use. In that case, you will be given the opportunity to view the photographs before you give permission for their use if you so request.

WHAT ARE THE COSTS?

There is no cost to you for the meals, dietary information, blood analyses, and the brain scan images of your brain that are all part of this research study. Parking is also free of charge at McKee Gymnasium, Patient Parking at the Hospital, and the Brain Imaging Center. The only cost you will have is the cost with traveling to and from the University of Missouri.

WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

You will be compensated a total of \$600 for completing all study procedures. Specifically, you will be paid \$150 for completing each meal pattern which includes the 10-hour testing day and the 6 days of correctly following the specific meal pattern at home.

WHAT IF I AM INJURED?

It is not the policy of the University of Missouri to compensate human participants in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to participants who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate. If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future care in the institution. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the Investigator of this study may decide to end your participation in this study at any time after she has explained the reasons for doing so and has helped arrange for your continued care by your own doctor, if needed.

You will be informed of any significant new findings discovered during the course of this study that might influence your health, welfare, or willingness to continue participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Health Sciences Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-3181.

You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact Heather J. Leidy, Primary Investigator, at 573-882-0654.

A copy of this consent form will be given to you to keep.

SIGNATURE

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. I have read this consent form and my questions have been answered. My signature below indicates my willingness to participate in this study.

Participant (if ≥ 18 years of age)	Date
Participant – Assent to Participate (if between the ages of 16-17 years)	Date
Legal Guardian/Advocate/Parent	Date
Additional Signature (if required); Identify relationship to Participant	Date

SIGNATURE OF STUDY REPRESENTATIVE

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered questions regarding the study to the best of my ability.

BLOOD STORAGE

blood samples retained.

<u>I agree</u> to allow the use of my blood samples collected during this study to be used for future research that might be unrelated to this study. The blood samples will be stored for 10 years. These samples will likely be used for future analysis of food intake and appetite hormones that have not yet been identified or are currently unable to be measured. The use and disclosures of personal information listed in the consent form also apply to the saved blood samples. However, at any time, I can request that the blood samples be destroyed if I change my mind. If this occurs, I will provide a written request to Dr. Leidy at 204 Gwynn Hall; University of Missouri; Columbia, MO 65211. Lastly, I understand that Dr. Leidy can use and share information that was gathered before this request was received.

Participant (if \geq 18 years of age)	Date	
Participant – Assent to Participate (if between the ages of 16-17 years)	Date	
Legal Guardian/Advocate/Parent	Date	
OR		
I request my blood samples collected during this study to NOT be used f is unrelated to this study. I understand that I can still participate in this s	•	

Participant	Date
Participant – Assent to Participate (if between the ages of 16-17 years)	Date
Legal Guardian/Advocate/Parent	Date

APPENDIX E. CHAPTER 4 CONSENT & ASSENT FORMS

PARENT OF RESEARCH PARTICIPANT STUDY CONSENT FORM

Benefits of Breakfast in the Classroom Heather J. Leidy, PhD Associate Professor Nutrition Science Purdue University

This consent may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

This is a research study being conducted by Dr. Heather Leidy at Purdue University.

Research studies include only people who choose to participate. As a parent of a study participant, you have the right to know about the tasks and activities that will be used in this research study so you can make the decision whether or not to participate. The information presented here is simply to make sure you understand so that you may give your approval for your child to participate in this research study. Please take your time to make your decision and talk about it with your family and friends.

Your child is being asked to take part in this study because your child attends Center Middle School which will be implementing a 'Breakfast in the Classroom' program. In order for your child to participate in this study, you must give your written assent.

Please note: regardless of whether your child participates in this study, your child will still be able to participate in 'Breakfast in the Classroom.'

What is the purpose of this study?

The purpose of this study is to determine whether 'Breakfast in the Classroom' increases breakfast consumption and improves overall health and well-being. In addition, we want to determine whether different foods provided at breakfast improve these outcomes.

This research is being done because we currently do not know whether school breakfast programs that allow the students to consume breakfast in their classrooms is beneficial for overall health and well-being.

How many people will take part in the study?

We expect that up to 550 students will take part in the study.

What will my child do if I choose to allow his/her to be in this study?

At school your child will complete the following tasks <u>at the beginning and end</u> of the study. The study is 8 weeks in duration. Also, all questionnaires will be completed using either student Chromebooks or as paper forms.

1) Body Weight, Height, and Body Composition: (ESTIMATED TIME: 5 min/time) For one day at the beginning and end of the study, your child will have his/her body weight and percent body fat measured using a research scale in a private room. Also at this time, height will be measured using a wall-mounted ruler in a private room.

2) Characteristics and Breakfast Habits Questionnaires: (ESTIMATED TIME: 5 min/time) For one day at the beginning and end of the study, your child will complete a questionnaire that ask some questions about his/her age, gender, ethnicity, race, and breakfast habits.

At school your child will complete the following tasks <u>at the beginning, middle, and/or end of the</u> <u>study</u>.

3) Appetite & Mood Questionnaires: (ESTIMATED TIME: 30 sec/questionnaire) For 3 days at the beginning, middle, and end of the study, your child will complete questionnaires that asks about his/her feelings of hunger, fullness, food cravings, mood, and energy levels. The questionnaires are completed before breakfast, immediately after breakfast, 1 h and 2 h after breakfast, and right before lunch.

4) Snacking Questionnaires: (ESTIMATED TIME: 5 min/questionnaire) For one day at the beginning , middle, and end of the study, your child will complete a questionnaire that asks about his/her snacking behavior and foods that are typically eaten at school and at home.

5) Cognitive Performance: (ESTIMATED TIME: 20 min/questionnaire) For one day at the beginning and end of the study Your child will complete a series of 'computer games' that estimate attention, memory, decision making, and the ability to multi-task.

6) Breakfast in the Classroom Questionnaires: (ESTIMATED TIME 30 sec/questionnaire) For 5 days at the beginning, middle, and end of the study, your child will complete a questionnaire that ask some questions about how much breakfast was eaten and thoughts on breakfast foods.

At school your child will complete the following tasks <u>at the middle and end of the study</u>.

7) Breakfast in the Classroom Waste: (ESTIMATED TIME 5 sec/task) For 5 days at the end of the study, your child will eat breakfast (as normal). However, when he/she is finished, he/she will place all containers and uneaten foods into a Ziploc bag and will place these into the classroom bin to assess waste.

How long will my child be in the study?

We expect your child to be in the study for 9 weeks. This will include Baseline (Week 0);4-weeek midstudy; and 8-week post-study measures.

You can stop your child from participating at any time. Your decision to withdraw your child from the study will not affect in any way your child's medical care and/or benefits. Further, your child will still be offered the same breakfasts as everyone else in his/her classroom.

What are the possible risks or discomforts?

The only potential risk is feeling uncomfortable or nervous in having body weight and height measures completed or answering questions about himself/herself. All information is confidential and will not be shared with anyone other than the study staff.

Are there any potential benefits?

If you agree to allow your child to participate in this study, there may or may not be direct benefit to your child. He/she may expect to benefit to the extent that he/she is helping with increases in health knowledge. We hope the information learned from this study will benefit other schools considering serving 'Breakfast in the Classroom.' Your child may receive benefits from this study by understanding why his/her current eating habits are unhealthy and might lead to increased overeating, weight gain, and obesity. This study may show your child which eating habits might be beneficial in order to reduce these unhealthy and unwanted behaviors. There is no guarantee that participating in this project will improve your child's eating habits.

What alternatives are available?

An alternative is to not participate in this research study.

Will I receive payment or other incentive?

Your child will be compensated with a \$25 gift card for participating in the study. The gift card will be given to you at the end of the study.

Are there costs to me or my child for participation?

There is no cost to you or your child for participating in the study.

What happens if my child becomes injured or ill because he/she took part in this study?

If you feel your child has been injured due to participation in this study, please contact Heather J. Leidy, PhD. (Primary Investigator) at 573-825-2620 or email: <u>hleidy@purdue.edu</u>. Purdue University will not provide medical treatment or financial compensation if your child is injured or become ill as a result of participating in this research project. This does not waive any of your or your child's legal rights nor release any claim you might have based on negligence.

Will information about my child and his/her participation be kept confidential?

The project's research records may be reviewed by the departments at Purdue University responsible for regulatory and research oversight.

The project's research records may be reviewed by the Purdue University Institutional Review Board, the Purdue Office for Human Research Protection, Office for Human Research Protections, by departments at Purdue University responsible for regulatory and research oversight.

Original paper copies of all identifiable data will be kept indefinitely in locked storage cabinets and rooms which are only accessible by Dr. Leidy, her research staff, and selected members of her department's information technology resources staff. All data will be de-identified prior to data entry and statistical analyses. There is a risk of breach of subject confidentiality but safeguards are in place to minimize this risk as outlined above.

What are my child's rights if he/she take part in this study?

Your child's participation in this study is voluntary. You may choose not to allow your child to participate or, if you agree to allow him/her to participate, you can withdraw your consent at any time without penalty or loss of benefits to which your child is otherwise entitled. Further, your child will still be offered the same breakfasts as everyone else in his/her classroom.

Who can I contact if I have questions about the study?

If you have questions, comments or concerns about this research project, you can talk to one of the researchers. Please contact Heather J. Leidy, PhD at 573-825-2620 or email: <u>hleidy@purdue.edu</u>.

If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email (irb@purdue.edu) or write to:

Human Research Protection Program - Purdue University Ernest C. Young Hall, Room 1032 155 S. Grant Street, West Lafayette, IN 47907-2114

Documentation of Informed Consent

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research study, and my questions have been answered. I am prepared to allow my child to participate in the research study described above. I will be offered a copy of this consent form after I sign it.

Participant Name (print)

Participant Parent

Investigator

Date

Date

Assent Form

Benefits of a Higher Protein, 'Egg-cellent' Breakfast in the Classroom

Investigators: Heather Leidy, PhD & Steve Douglas, Doctoral Student

We are doing a research study. A research study is a special way to find out about something. Your school is starting a new breakfast program that is free for all students. We want to find out if that breakfast program helps you feel and think better.

This study is voluntary. It will not affect you classes, class work, class grades, or any other opportunities or things provided to you at school. All students in the school will receive the school's breakfast meals each day.

The study is 2 months long. If you decide that you want to be in this study, here are some of the things you will be doing. All study tasks are done at school. During the study, you will answer questions about your eating habits, appetite, and mood. Your body weight, height, and how much you eat at breakfast will be measured. Finally, you will play a computer 'game' that measures your attention, memory, decision-making ability, and your ability to multi-task.

We want to tell you about some things that might happen to you if you are in this study. You may feel uncomfortable or nervous about having your body weight and height measured or about answering questions about yourself. All information is kept secret and will not be shared with anyone other than study staff. The school does not see your information.

If you decide to be in this study, some good things might happen to you. You will help us determine if the school's breakfast program helps students think and feel better. You may also learn what makes you think and feel better. But we don't know for sure that these things will happen.

When we are done with the study, you will be given a \$25 gift card for participating in the study. We will also write a report about what we found out. We won't use your name in the report.

You don't have to be in this study. You can say "no" and nothing bad will happen. If you say "yes" now, but you want to stop later, that's okay too. No one will hurt you, or punish you if you want to stop. All you have to do is tell us you want to stop.

If you want to be in this study, please write your name below.

_____, want to be in this research study.

(write your name here)

Investigator signature

I, _____

(Date)

APPENDIX F. CHAPTER 5 CONSENT & ASSENT FORMS

PARENT OF RESEARCH PARTICIPANT <u>STUDY CONSENT FORM</u>

Purdue Study for the Benefits of Breakfast in the Classroom Heather J. Leidy, PhD Associate Professor in the Dept. of Nutrition Science

Purdue University

What is the Purpose of this Study?

As you are aware, the Center Middle School is starting a 'Breakfast in the Classroom' program. This breakfast program is free and available to all students within the Center Middle School.

We (Professor Heather Leidy and her research team at Purdue University) are doing a research study within the Center Middle School to determine whether 'Breakfast in the Classroom' increases breakfast consumption and improves overall health and well-being. In addition, we want to determine whether different foods provided at breakfast improve these outcomes.

This study is voluntary. It will not affect your child's classes, class work, class grades, or any other opportunities or things provided to your child at school.

In order for your child to participate in this study, you must give your written consent and your child must also give assent. *Please note that regardless of whether your child participates in this research study, your child will still be able to participate in 'Breakfast in the Classroom.'*

How many people will take part in the study?

We expect that up to 700 students will take part in the study.

How long will my child be in the study?

We expect that your child will be in the study for approximately 6 months.

What will my child do if I choose to allow him/her to be in the study?

Throughout the study, the following things will be completed:

- Your child's body weight, height, and body composition will be measured in a private room using a scale and a wall-mounted ruler.
- Your child will complete short surveys that will take 10 sec 10 min to complete. Your child can complete the surveys on the computer or with paper and pencil/pen. The surveys ask information about your child such as his/her age, gender, ethnicity, race, appetite, mood, energy levels, eating habits, and thoughts about the 'Breakfast in the Classroom' program.
- Your child will participate in computer 'games' to help the researchers measure your child's attention, memory, decision making, and the ability to multi-task.
- Leftover food following breakfast waste will be measured by having your child place all uneaten foods in classroom bins.

You can stop your child from participating at any time. Your child can also choose to stop at any time. The decision to withdraw your child from the research study will not affect in any way your child's relationship with the school. Further, your child will still be offered the same breakfasts as everyone else in his/her classroom he/she ends participation in the research study.

What are the possible risks or discomforts?

A potential risk to your child is that your child may feel uncomfortable or nervous while having his/her body weight and height measures completed or answering questions about himself/herself. With all research there is a risk that the information collected could viewed by unapproved individuals. The research team has procedures in place to help lessen this risk, these steps can be found in the confidential section below.

Are there any potential benefits?

If you agree to allow your child to participate in this study, there may or may not be direct benefit to your child. He/she may expect to benefit to the extent that he/she is helping with increases in health knowledge. We hope the information learned from this study will benefit other schools considering serving 'Breakfast in the Classroom.' Your child may receive benefits from this study by understanding why his/her current eating habits are unhealthy and might lead to increased overeating, weight gain, and obesity. This research study may show your child which eating habits might be helpful in order to lower these unhealthy and unwanted behaviors. There is no guarantee that participating in this research study will improve your child's eating habits.

Will my child receive payment or other incentive?

Your child will be compensated with a \$25 gift card for completing all study procedures. The gift card will be given to your child at the end of the research study.

Are there costs to me or my child for participation?

There is no cost to you or your child for participating in the research study.

What happens if my child becomes injured or ill because he/she took part in this study?

If you feel your child has been injured due to participation in this study, please contact Heather J. Leidy, PhD. (Primary Investigator) at 573-825-2620 or email: <u>hleidy@purdue.edu</u>. Purdue University will not provide medical treatment or financial compensation if your child is injured or become ill as a result of participating in this research project. This does not waive any of your or your child's legal rights nor release any claim you might have based on negligence.

Will information about my child and his/her participation be kept confidential?

The project's research records may be reviewed by the departments at Purdue University responsible for regulatory and research oversight.

Original paper copies of data collected from your child that could identify him/her will be kept for 10 years in locked storage cabinets and rooms which are only accessible by Professor Leidy, her research staff, and selected members of her department's information technology resources staff. Information that could identify your child will be removed and destroyed before the researchers begin to exam and analyze the information collected. If the information that is found through examining and studying the data that was collected will be published for the general public no information that could personally identify your child will be used.

What are my child's rights if he/she take part in this study?

Your child's participation in this research study is voluntary. You may choose not to allow your child to participate or, if you agree to allow him/her to participate, you can withdraw your consent at any time without penalty or loss of benefits to which your child is otherwise entitled. Your child can also decide to stop at any time. Further, your child will still be offered the same breakfasts as everyone else in his/her classroom if he/she stops the research study early.

Who can I contact if I have questions about the study?

If you have questions, comments or concerns about this research project, you can talk to one of the researchers. Please contact Heather J. Leidy, PhD at 573-825-2620 or email: <u>hleidy@purdue.edu</u>.

If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email (irb@purdue.edu) or write to:

Human Research Protection Program - Purdue University Ernest C. Young Hall, Room 1032 155 S. Grant Street, West Lafayette, IN 47907-2114

Documentation of Informed Consent

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research study, and my questions have been answered. I am prepared to allow my child to participate in the research study described above. I will be offered a copy of this consent form after I sign it.

Participant (Child's) Name (print)

Parent's Name (of Participating Child)

Investigator

Date

Date

Assent Form

Purdue Study for the Benefits of Breakfast in the Classroom

Primary Investigator: Heather Leidy, PhD

We are doing a research study. A research study is a special way to find out about something. Your school is starting a new breakfast program that is free for all students. We want to find out if that breakfast program helps you feel and think better.

This study is voluntary. It will not affect your classes, class work, class grades, or any other opportunities or things provided to you at school. All students in the school will receive the school's breakfast meals each day.

The study is approximately 6 months long. If you decide that you want to be in this study, here are some of the things you will be doing. All study tasks are done at school. During the study, you will answer questions about your eating habits, appetite, and mood. Your body composition and height will be measured. You will answer questions about your likes and dislikes with breakfast. We will measure how much you eat at breakfast. Finally, you will play a computer 'game' that measures your attention, memory, decision-making ability, and your ability to multi-task.

We want to tell you about some things that might happen to you if you are in this study. You may feel uncomfortable or nervous about having your body composition and height measured or about answering questions about yourself. All information is kept secret and will not be shared with anyone other than study staff. The school does not see your information.

If you decide to be in this study, some good things might happen to you. You will help us determine if the school's breakfast program helps students think and feel better. You may also learn what makes you think and feel better. But we don't know for sure that these things will happen.

When we are done with the study and have completed all study procedures, you will be given a \$25 gift card. We will also write a report about what we found out. We will not use your name in the report.

You do not have to be in this study. You can say "no" and nothing bad will happen. If you say "yes" now, but you want to stop later, that is okay too. No one will hurt you, or punish you if you want to stop. All you have to do is tell us you want to stop.

If you want to be in this study, please write your name below.

_____, want to be in this research study.

(write your name here)

Investigator signature

I, ___

(Date)

VITA

Steve M. Douglas

700 West State St., room G54 Dept. of Nutrition Science West Lafayette, IN 47907 Email: dougla53@purdue.edu

EDUCATION

2010 - 2014	B.S. Nutritional Sciences Department of Nutrition & Exercise Physiology Minors in Philosophy and Psychology University of Missouri, Columbia, MO GPA: 3.96/4.0
2015 - 2016	Pursued a doctoral degree in Nutrition Sciences Department of Nutrition and Exercise Physiology University of Missouri, Columbia, MO GPA: 3.86/4.0
2016 - 2019	PhD. Nutrition Sciences Department of Nutrition Science Purdue University, West Lafayette, Indiana GPA: 4.0/4.0

PROFESSIONAL/EMPLOYMENT EXPERIENCE

Aug 2016 – June 2019	Graduate Research Assistant
	Dept. of Nutrition Science
	Purdue University
	West Lafayette, IN 47907
	Advisor: Heather J. Leidy, PhD
	Responsibilities: Plan studies, organize material necessary for Institutional
	Review Board review and testing day procedures, prepare testing day equipment, complete testing day procedures, set up information session, screen potential participants, analyze data from studies, publish and present the data.

Aug 2016 – Dec 2016	Teaching Assistant – Food Chemistry (Lab)Dept. of Nutrition Science700 West State StreetPurdue UniversityWest Lafayette, IN 47907Supervisor: Cordelia Running, PhDResponsibilities: Prepare lab equipment prior to class, prepare PowerPoints for students, administer quizzes, assist in completion of required lab, and answer questions from class.Reason for leaving: Contracted ended (seasonal employment)
Aug 2015 – Aug 2016	Graduate Research Assistant Dept. of Nutrition and Exercise Physiology 204 Gwynn Hall University of Missouri Columbia, MO 65211 Advisor: Heather J. Leidy, PhD Responsibilities: Plan studies, organize material necessary for Institutional Review Board review and testing day procedures, prepare testing day equipment, complete testing day procedures, set up information session, screen participants, analyze data from studies, publish and present the data. Reason for leaving: Transferred to Purdue University (advisor moved)
May 2014 – Aug 2015	Academic Tutor and Mentor Intercollegiate Athletics 1 Champions Drive University of Missouri Columbia, MO Supervisor: Nicolle Lewis Responsibilities: Assist athletes in fulfilling their academic obligations and answer questions that may have come up from studying the material in class. Reason for leaving: Began graduate school. Courses Taught/Tutored: Introductory Biology, Anatomy and Physiology, Chemistry (all levels), Organic Chemistry (all levels), Genetics, Biochemistry (all levels) Introduction to Nutrition, Introduction to Exercise Sciences, Introduction to Psychology.
May 2011 – Aug 2011	<i>Family Programmer</i> The YMCA of the Rockies – Estes Park Center 2515 Tunnel Road Estes Park, CO 80511 Supervisor: Paul Taylor Responsibilities: Lead a variety of educational and/or activity based family programs for guests. Reason for leaving: Contracted ended (seasonal employment)

Jan 2011 – May 2014 <u>Undergraduate Research Assistant</u> Dept. of Nutrition & Exercise Physiology 204 Gwynn Hall University of Missouri Columbia, MO 65211 Research Advisor: Heather J. Leidy, PhD Responsibilities: Prepare testing day equipment, complete testing day procedures, set up information session, screen participants, analyze data from studies, publish and present the data. Reason for leaving: Graduated

RESEARCH INTERESTS

As a translational, nutritional physiologist, I examine the mechanisms by which the consumption of breakfast and breakfast composition improves weight management and cognitive function; and seek to apply these findings to community/school-based interventions. Specific focus areas include the effects of breakfast and breakfast composition on weight management, snacking behavior, acute cognitive performance and neural structural changes controlling appetite, food cravings, and cognitive function.

PUBLICATIONS

- 1) Leidy HJ, Hoertel JA, **Douglas SM**, Higgins KA, Shafer RS. A protein breakfast reduces daily intake, hunger, and prevents body fat gain in overweight 'breakfast skipping' adolescents; *Obesity*; Sept; 23(9): 1761-4; 2015
- 2) Bauer LB, Reynolds LJ, Douglas SM, Kearney ML, Hoertel HA, Shafer RS, Thyfault JP, Leidy HJ. A pilot study examining the effects of consuming a high-protein vs. normal-protein breakfast on free-living glycemic control in overweight/obese 'breakfast skipping' adolescents; *International Journal of Obesity*; Sept; 39(9): 1421-4; 2015
- 3) **Douglas SM**, Lasley TR, Leidy HJ. Consuming beef vs. soy protein has little effect on appetite, satiety, and food intake in healthy adults; *Journal of Nutrition;* May; 145(5): 1010-6; 2015
- 4) Ortinau JC, Hoertel HA, **Douglas SM**, Leidy HJ. Effects of higher protein vs. higher fat snacks on appetite control, satiety, and eating initiation in healthy women. *Nutrition Journal*; 13(97); 2014
- 5) Ortinau LC, Culp JM, Hoertel HA, **Douglas SM**, Leidy HJ. The effects of increased dietary protein in afternoon yogurt snacks on appetite control and eating initiation in healthy women. *Nutrition Journal*; 12(71); 2013
- 6) Leidy HJ, Ortinau LC, **Douglas SM**, Hoertel HA. Benefits of a protein-rich breakfast on the appetitive, hormonal, and neural signals controlling energy intake regulation to combat obesity in late-adolescent females. *American Journal of Clinical Nutrition*; 97(4): 677-88; 2013
- 7) **Douglas SM**, Ortinau LC, Hoertel HA, Leidy HJ. Low, moderate, or high protein yogurt snacks on appetite control and subsequent eating in healthy women. *Appetite;* 60; 117-122; 2013

PUBLICATIONS IN PROGRESS

- 1) **Douglas SM**, Gwin JA, Leidy HJ. Effects of consuming protein shakes, varying in protein source, on appetite, satiety and energy intake.
- 2) **Douglas SM**, Gwin JA, Leidy HJ. Novel methodological considerations regarding the use of visual analog scale questionnaires to assess appetite control and satiety
- 3) **Douglas SM**, Byers AW, Leidy HJ. Habitual breakfast patterns do not influence appetite and satiety responses to normal versus high-protein breakfasts in overweight adolescents
- 4) **Douglas SM**, Braden ML, Kruse M, Leidy HJ. A free, egg-based 'Breakfast in the Classroom' program improves school breakfast participation and eating in middle-school adolescents
- 5) **Douglas SM**, Kruse M, Leidy HJ. Students who participate in 'Breakfast in the Classroom' perform better on tasks assessing cognitive flexibility and executive function
- 6) **Douglas SM** and Leidy HJ. A review of school breakfast programs and their effects on weight management, diet quality, and cognitive performance A focus on novel school breakfast programs

AWARDS & HONORS

2017	Purdue University, Purdue Graduate Student Government Travel Award
2016	University of Missouri, F21C – Nutrition, Student Travel Award
2015	College Ready & Learning Association, Level 1 Certified Tutor
2014	University of Missouri, Sum Cum Laude Latin Honor
2010 - 2014	University of Missouri, Academic Honor Roll
2012	 University of Missouri, Department of Nutrition & Exercise Physiology Human Environmental Sciences Research Fellowship

• Undergraduate Research Travel Award

CURRENT GRANTS

HJ Leidy (PI); SM Douglas (PhD Student) Egg Nutrition Center

Title: The acute benefits of an 'Egg-Cellent' Breakfast in the Classroom on breakfast consumption, snacking behavior, and cognitive function in middle school students

Objectives: To examine whether the implementation of a novel high-protein 'Breakfast in the Classroom' program improves school breakfast participation, breakfast quality, and snacking habits compared to a normal-protein 'Breakfast in the Classroom' program.

4/1/18 - 5/30/18

Role: Doctoral Student; assist with development of protein-based school breakfast program, preparation of procedures; distribution of surveys; outcome collection; write-up results for publication

SM Douglas (PhD Student); R Mattes (PI); HJ Leidy (Mentor/Supervisor) <u>NIH T32 5T32DK076540-08</u> (\$84,772 Direct/Total)

Title: Interdisciplinary Training in Signals Controlling Ingestion and Obesity Objectives of training grant: To train predoctoral students for the study of healthful and dysfunctional feeding to address the problem of obesity.

Student Objectives: Applying our current breakfast research findings collected from clinical, tightlycontrolled, mechanistic studies towards a school-based, practical approach. This involves working collaboratively to develop a novel protein-based 'Breakfast in the Classroom' program in conjunction with a USDA-supported breakfast program at the Center Middle School in Kansas City, KS. 8/1/18-8/1/19

Role: Doctoral Student; assist with development of protein-based school breakfast program, preparation of procedures; distribution of surveys; outcome collection; write-up results for publication

HJ Leidy (PI); SM Douglas (PhD Student) National Institutes of Health (NIH)- 1 R01 DK107390-01A1

(\$2,468,708 Direct; \$3,624,885 Total)

Title: Increased protein at breakfast for weight management in overweight adolescents Objective: 1) to determine whether a causal link exists between breakfast, particularly one rich in dietary protein, and weight management in young people; 2) to identify the appetitive, hormonal, and neural signals by which a protein breakfast modulates ingestive (i.e., eating) behavior and weight management; and 3) to identify specific appetitive, hormonal, and neural signals as strong predictors of ingestive behavior and weight management.

9/1/17 -8/31/21

Role: Doctoral Student; Assist with testing day preparation and procedures

HJ Leidy (PI); SM Douglas (PhD Student) Sabra

Title: The benefits of consuming hummus as an afternoon snack on appetite control, daily food intake, and diet quality in adults

Objectives: We propose a randomized crossover study to examine the effects of consuming hummus as an afternoon snack on appetite control, daily food intake, and diet quality in healthy adults 12/1/17 - 5/7/19

Role: Doctoral Student; Assist with testing day preparation and procedures

HJ Leidy (PI); SM Douglas (PhD Student) Roquette

Title: The Effects of Protein Source on Appetite Control, Satiety, and Subsequent Food Intake: A Clinical Screening Study

Objectives: To examine whether the consumption of preloads varying in protein quality effect subsequent meal energy and macronutrient content; postprandial feelings of hunger, fullness, desire to eat, prospective food consumption, and eating initiation; and postprandial cognitive performance. 12/1/17 - 1/31/19

Role: Doctoral Student; Assist with testing day preparation and procedures

PAST GRANTS

HJ Leidy (PI); SM Douglas (PhD Student) Egg Nutrition Center (\$30,000 Direct/Total)

Title: The acute benefits of an 'Egg-Cellent' Breakfast in the Classroom on breakfast consumption, snacking behavior, and cognitive function in middle school students

Objectives: To examine whether the implementation of a novel high-protein 'Breakfast in the Classroom' program improves school breakfast participation, breakfast quality, and snacking habits compared to a traditional school breakfast program.

4/1/18 - 5/30/18

Role: Doctoral Student; assist with development of protein-based school breakfast program, preparation of procedures; distribution of surveys; outcome collection; write-up results for publication

HJ Leidy (PI); SM Douglas (PhD Student)

Leprino Foods

Title: The Effects of Protein Source on Appetite Control, Satiety, and Subsequent Food Intake *Objectives: To examine whether the consumption of breakfast meals that vary in protein quality effect the post-prandial appetitive, hormonal, and ingestive behavior responses across the day.* 11/1/16 - 10/30/18

Role: Doctoral Student; Assist with testing day preparation and procedures

SM Douglas (PI); HJ Leidy (Mentor/Supervisor) Egg Nutrition Center Student Fellowship (\$20,000 Direct/Total)

Title: Identifying the effects of egg consumption at breakfast on improvements in cognitive performance in overweight/obese adolescents

Objectives: 1) To examine whether the daily consumption of breakfast improves cognitive performance in 'breakfast skipping' teens. 2) To identify whether breakfast improves cognitive performance through alterations in structural and functional changes within select brain regions in breakfast skipping teens. 8/1/17-7/31/18

Role: Doctoral Student; Assist with testing preparation and procedures; write-up results for publication

HJ Leidy (PI); SM Douglas (PhD Student) Beef Checkoff

Title: Long-term effects of consuming a high protein, beef breakfast on weight management and glycemic control in overweight 'breakfast-skipping' young people

Objectives: 1) To examine the effects of breakfast consumption on weight management and glycemic control; and 2) assess the feasibility of consuming a high protein breakfast in a free-living environment. 10/1/15-9/31/16

Role: Doctoral Student; Assist with testing day preparation and procedures

SM Douglas (PI); HJ Leidy (Mentor/Supervisor)

Rembrandt Foods Student Fellowship (\$20,000 Direct/Total)

Title: Egg Albumen Protein Absorption and Muscle Synthesis

Objectives: 1) To review, organize and summarize all existing clinical research around the topic of egg albumen proteins in sports nutrition. 2) To suggest and perform an experiment evaluating the differential effects of protein source (whey, casein, and egg) on satiety.

1/1/16-6/30/16

Role: Doctoral Student; Review current literature and suggest/perform an experiment evaluating the differential effects of protein source (whey, casein, and egg) on satiety.

HJ Leidy (PI); SM Douglas (Undergraduate Honors Student) Beef Checkoff

Title: Effects of Protein Quality on Appetite Control, Reward-driven Eating, & Subsequent Food Intake: Comparison of Animal vs. Plant-based Proteins – Additional Analyses

Objective: to more extensively examine the relationship between plasma amino acid responses and the appetite and hormonal signals controlling ingestive behavior.

1/1/14-4/30/14

Role: Undergraduate Student; Assist with testing day preparation and procedures, analyze results, and synthesize final publication

HJ Leidy (PI); SM Douglas (Undergraduate Honors Student) <u>The Beef Checkoff</u>

Title: Effects of protein quality on appetite control, reward-driven eating, and subsequent food intake: comparison of animal vs. plant-based proteins

Objective: to provide evidence supporting the consumption of high quality beef protein vs. plant-based protein foods to improve short-term appetite control, reward-driven eating behavior, & energy intake regulation in healthy adults.

5/01/12-7/28/13

Role: Undergraduate Student; Assist with testing day preparation and procedures, analyze results, and synthesize final publication

HJ Leidy (PI); SM Douglas (Undergraduate Honors Student) <u>The Pork Checkoff</u>

Title: The Daily consumption of a protein-rich breakfast for long-term improvements In appetite, glucose control, and body weight management in overweight & obese 'breakfast skipping' adolescents *Objective: to identify whether the daily addition of a protein-rich, pork-based breakfast leads to beneficial changes in daily appetite & satiety, glucose control, food intake, & body weight/composition compared to the daily consumption of normal protein, cereal-based breakfast meals.* 1/01/11-7/01/12

Role: Undergraduate Student; Assist with testing day preparation and procedures

HJ Leidy (PI); SM Douglas (Undergraduate Honors Student) General Mills Bell Institute of Health

Title: The beneficial effects of Yoplait®'s protein-rich Greek Yogurt as a healthy, afternoon snack on appetite control, satiety power, & subsequent meal request

Objective: to identify the benefits of consuming higher protein, Greek yogurt as an afternoon snack on appetite control, satiety, and timing to meal request in young to middle-age women. 5/31/11-12/31/11

Role: Undergraduate Student; Analyze results and synthesize final publication

HJ Leidy (PI); SM Douglas (Undergraduate Honors Student) Egg Nutrition Center & The Beef Checkoff

Title: The beneficial effects of a protein-rich breakfast on appetite control, body weight management, & cognition in overweight and obese adolescents *Objective: to provide mechanistic evidence supporting the addition of a protein-rich breakfast to*

improve and/or re-establish short-term appetite control, and energy intake regulation in overweight/obese 'breakfast skipping' adolescents. 7/01/10-10/31/11

Role: Undergraduate Student; Assist with testing day preparation and procedures

POSTER PRESENTATIONS

2018	American Society of Nutrition Annual Meeting, Boston, MA June 2018 Douglas SM, Byers A, Leidy HJ (2018). Effects of Breakfast Type and Habitual Breakfast Patterns on Morning Appetite and Satiety in Overweight Late Adolescent Girls
2017	May Conference, May 2017 Douglas SM, Gwin JA, Leidy HJ (2017). Effects of consuming protein beverages, varying in protein source, on appetite, satiety and energy intake
2017	Experimental Biology Annual Meeting, Chicago, IL April 2017 Douglas SM, Gwin JA, Leidy HJ (2017). Effects of consuming protein beverages, varying in protein source, on appetite, satiety and energy intake
2017	Interdepartmental Nutrition Program Day, October 2017 Douglas SM, Gwin JA, Leidy HJ (2017). Effects of consuming protein beverages, varying in protein source, on appetite, satiety and energy intake
2016	Health and Human Sciences Research Week, October 2016 Douglas SM, Gwin JA, Leidy HJ (2016). Effects of consuming protein beverages, varying in protein source, on appetite, satiety and energy intake
2014	Experimental Biology Annual Meeting, San Diego, CA April 2014 Douglas SM, Lasley TR, Ortinau LC, Shafer RS, Leidy HJ (2014). The consumption of one serving of beef vs. one serving of soy at lunch on appetite control, satiety, and subsequent energy intake: A practical comparison.

2014	Life Sciences Week, University of Missouri, April 2014 Douglas SM, Lasley TR, Ortinau LC, Shafer RS, Leidy HJ (2014). The consumption of one serving of beef vs. one serving of soy at lunch on appetite control, satiety, and subsequent energy intake: A practical comparison.
2012	Experimental Biology Annual Meeting, San Diego, CA April 2012 Douglas SM, Ortinau LC, Hoertel HA, Leidy HJ (2012). Low, moderate, or high protein yogurt snacks on appetite control and subsequent eating in healthy women
2012	Nutrition and Exercise Physiology Research Week, March 2012 Douglas SM, Ortinau LC, Hoertel HA, Leidy HJ (2012). Low, moderate, or high protein yogurt snacks on appetite control and subsequent eating in healthy women

ORAL PRESENTATIONS

2012	Experimental Biology Annual Meeting, San Diego, CA April 2012 Douglas SM, Ortinau LC, Hoertel HA, Leidy HJ (2012). Low, moderate, or high protein yogurt snacks on appetite control and subsequent eating in healthy women
2014	Experimental Biology Annual Meeting, San Diego, CA April 2014 Douglas SM, Lasley TR, Ortinau LC, Shafer RS, Leidy HJ (2014). The consumption of beef vs. soy lunch meals on food cravings & cortico-limbic brain regions in healthy adults
2017	Experimental Biology Annual Meeting, Chicago, IL April 2017 Douglas SM, Gwin JA, Leidy HJ (2017). Novel methodological considerations regarding the use of visual analog scale questionnaires to assess appetite control and satiety

PROFESSIONAL MEMBERSHIP

2015 - present	 American Society of Nutrition, Student Member Energy and Macronutrient Metabolism Research Interest Group Obesity Research Interest Group
2018 – present	Society for the Study of Ingestive Behavior
SERVICE	

2017 – 2018 Friendship House, Volunteer

STUDENT MENTORING

2017-2019	Morgan Braden; Undergraduate student, Nutrition Science; Purdue University
2017-2019	Evan Reister; Graduate student, Nutrition Science; Purdue University
2017-2019	Adam Byers; Undergraduate student, Nutrition Science; Purdue University
2017-2018	Ashley Swain; Undergraduate student, Didactic Program in Nutrition and Dietetics; Purdue University
2015 - 2016	Erica Braham; Undergraduate student, Exposure to Research for Science Students (EXPRESS); Health Sciences; University of Missouri
2015 2016	Emily Shaw; Undergraduate student, Nutritional Sciences; University of Missouri
2015 - 2016	Sabrina Reed; Undergraduate student, Nutritional Sciences; University of Missouri
2013	Connor Roenfeldt; Undergraduate student, Nutrition & Fitness; University of Missouri
2013	Joe Douglas; Undergraduate student, Communications; University of Missouri
2012	Kelly Higgins; Undergraduate student, Nutritional Sciences; University of Missouri
2012	Andrea Boone; Undergraduate student, Biology; University of Missouri
2012	Kinsey Farren; Undergraduate student, Nutrition & Fitness; University of Missouri

COLLEGIATE ORGANIZATIONS/ACTIVITIES

Aug 2016 – May 2018	Ingestive Behavior Research Group, Member
	• Attend weekly meetings and participate in journal club
April 2018 – May 2018	 Nutritional Sciences Graduate Student Organization (NSGSO), Career Advocate Organize NSGSO speaker nominations Coordinate webinars with industry scientists
2010 - 2016	Columbia Rock Campus Church Member Attend weekly services and bible studies Student Leader Facilitate bible studies, coordinate weekly activities, and serve as greeter Staff Lead undergraduate student leaders and coordinate church wide activities
2011 & 2015	 Colorado Leadership Training, YMCA of the Rockies Participant Participate in bi-weekly church worship services and weekly small group activities Staff (2015 only) Lead student leaders, assist in facilitating small group activities, coordinate workshops.
2010 - 2013	 University of Missouri Premedical Society Member Attend Monthly meetings and participate in service opportunities Vice President of Membership (2013 only) Coordinate expenses, attendance, and membership