

EFFECTS OF A BREAKFAST IN THE CLASSROOM INITIATIVE ON  
CHILDHOOD OBESITY IN LOW-INCOME ETHNICALLY DIVERSE  
YOUTH: A RANDOMIZED CONTROL TRIAL

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## ABSTRACT

**Background:** School districts across the country have adopted breakfast in the classroom (BIC) initiatives as a means of increasing participation in the School Breakfast Program (SBP). Little is known regarding the impact of such programs on children's weight status. This study sought to evaluate the impact of a BIC initiative on the combined incidence of overweight/obesity among urban school aged children.

**Design:** Cluster-randomized controlled trial with matched school pairs. Intervention schools received the "One Healthy Breakfast" program included BIC, nutrition-education, social marketing, corner store marketing, and parent outreach, while control schools continued to serve breakfast in the cafeteria. Baseline data were collected in October-December, 2013, with midpoint and endpoint data collected in May-June 2015 and May-June 2016 respectively. Schools were matched based on school size, food service type, and racial/ethnic composition.

**Setting/Participants:** 1371 4th-6th grade students from sixteen K-8 public schools in Philadelphia, Pennsylvania with 50% of students eligible for free or reduced-price meals.

**Main Outcome and Measure:** Combined incidence of overweight/obesity was the primary outcome. Secondary outcomes included incidence of obesity, combined prevalence of overweight/obesity, prevalence of obesity, BMI-z scores, and SBP participation rates. Directly measured heights and weights were taken at baseline, midpoint, and endpoint; meal participation was gathered from Food Services staff.

**Results:** Of the 1371 baseline sample (51.3% female, 66.5% Black), 978 and 793 children completed midpoint and 793 endpoint measures respectively. At baseline, 58.4% of the sample was normal weight. There was no significant difference in combined incidence or prevalence of overweight/obesity or BMI z-scores at the midpoint nor endpoint. Incidence of obesity was significantly higher among intervention students than control students at the midpoint (7.1% vs. 4.3%) and endpoint (11.6% vs. 4.4%). The predicted odds of incident obesity over 2.5 years was 3 times higher in intervention schools than control schools (OR: 2.95, 95%CI: 1.54-5.64,  $p < 0.001$ ). SBP participation rates were significantly higher in the intervention schools than control schools between baseline and midpoint (79.3% vs. 19.6%, OR: 0.45, 95%CI: 0.35-0.56,  $p < 0.001$ ) and baseline and endpoint (61.6% vs. 14.8%, OR: 0.33, 95%CI: 0.20-0.45,  $p < 0.001$ ).

**Conclusions:** In conclusion, these findings suggest that BIC may be effective means of promoting SBP participation but does not prevent OW/OB among urban youth and may actually increase risk of OB among heavier “at risk” children. Based on these data, BIC should not be marketed as a childhood obesity prevention tool. More research is needed on alternative SBP delivery models, as well as the nutritional composition of school breakfast, in order to better understand how the SBP influences children’s consumption habits.

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## TABLE OF CONTENTS

ABSTRACT.....	ii
ACKNOWLEDGMENTS.....	iv
LIST OF TABLES.....	vii
LIST OF FIGURES.....	viii
CHAPTERS	
1. BACKGROUND.....	1
Defining and Measuring Childhood Obesity.....	2
Breakfast and Weight Status.....	4
The School Breakfast Program (SBP) .....	6
Current Study’s Contribution to the Literature.....	9
2. INTRODUCTION.....	11
3. MATERIALS/METHODS.....	14
Design and Sample.....	14
Intervention – The One Healthy Breakfast Program.....	17
Main Outcomes and Measures.....	19
Data and Analysis.....	22
4. RESULTS.....	24
Student Participation.....	24
Weight Status.....	25
SBP Participation.....	27
5. DISCUSSION.....	28
6. CONCLUSIONS.....	31

BIBLIOGRAPHY.....32

APPENDICES

A. IRB RE-APPROVAL LETTER.....43

B. SOCIAL/BEHAVIORAL RESEARCH COURSE.....44

## LIST OF TABLES

Table	Page
1. Baseline characteristics of 4 <sup>th</sup> -6 <sup>th</sup> Philadelphia public school students participating in the School Breakfast Policy Initiative (SBPI) study.....	24
2. Overweight and obesity outcomes at midpoint and endpoint.....	26
3. School Breakfast Program (SBP) participation rates.....	27

## LIST OF FIGURES

Figure	Page
1. Flow of participants through the trial.....	21

## **CHAPTER 1**

### **BACKGROUND**

The prevalence of childhood obesity has increased significantly over the past three decades. Recent data suggest that obesity in pre-school children aged 2-5 has decreased from 14% to 8% since 2003-2004 (Ogden et al., 2016), and overall childhood and adolescent overweight and obesity rates have begun to plateau (Frederick, Snellman, & Putnam, 2014; Ogden et al., 2016). According to the most recent National Health and Nutrition Examination Surveys (2011-2014), however, 17.0% of US children aged 2 to 19 were obese, while 5.8% were extremely obese (Ogden et al., 2016). Furthermore, the prevalence of childhood overweight and obesity is not equal across racial/ethnic groups nor socioeconomic status (Frederick et al., 2014; Singh, Siahpush, & Kogan, 2010). NHANES data demonstrates that obesity prevalence ranged from as low as 8.6% and 14.1% in Asian and White children, to as high as 20.2% in Black children, and 22.4% in Hispanic children (Ogden et al., 2016). Additionally, children living in low-income or low education households were 3.4-4.3 more likely to be obese than those children living in higher socioeconomic households (Singh et al., 2010). Comparisons between 2003 and 2007 National Survey of Children's Health data also reveal that although overall childhood obesity prevalence increased by 10% in the four year time frame, obesity prevalence among children living in low-education, low-income, and higher unemployment homes increased by 23-33% and by 24.2% in Hispanic children (Singh et al., 2010). These data indicate that childhood obesity remains a major national issue, and that the problem is especially dire among low-income youth.

Childhood obesity has been linked to a variety of health problems both during childhood and later in adulthood. In addition to increasing one's risk for many life threatening and debilitating diseases—hypertension, Type-2 Diabetes, sleep apnea, and musculoskeletal problems (Ebbeling, Pawlak, & Ludwig, 2002; Reilly & Kelly, 2011)—childhood obesity also has psychosocial consequences, as obese children and adolescents face various stigmas and prejudices which cause them to develop a negative self-image, low self-esteem, and feelings of loneliness and sadness (Ebbeling et al., 2002). Furthermore, research has demonstrated that due to additional prescription drugs, emergency room visits, and outpatient visits, childhood and adolescent overweight and obesity costs the nation approximately \$14.1 billion each year (Trasande & Chatterjee, 2009), and researchers predict that current adolescent overweight and obesity will result in 1.5 million life-years lost between 2020-2050 (Lightwood et al., 2009). As evident by these studies, childhood obesity impacts children's lives both in the short term and long term. Therefore, early prevention of obesity is crucial for population health.

### **Defining and Measuring Childhood Obesity**

Body mass index (BMI) is the most common indicator used for estimating adiposity (i.e., body fatness). Calculated from an individual's height and weight<sup>i</sup>, BMI is often used as a screening tool to identify overweight and obesity. For adults, normal weight is defined as a BMI between 18.5-24.9, overweight as a BMI between 25.0-29.9, and obese as a BMI $\geq$ 30 (Ogden et al., 2016). Due to varying body compositions across

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<sup>i</sup> BMI=(weight in kilograms)/(height in meters)<sup>2</sup>

and growth during childhood and adolescence, weight categories are defined differently for children aged 2-19 y. Standardized by age and sex, a child's BMI-for-age is compared to obesity and overweight cutoffs outlined by the Centers for Disease Control and Prevention's (CDC) pediatric growth charts. Originally developed by the National Center for Health Statistics (NCHS) in 1977 as a clinical tool for health professionals, these growth charts "consist of a series of percentile curves that illustrate the distribution of selected body measurements in U.S. children" (CDC, 2009). In 2000, the 1977 NCHS growth charts were revised using more comprehensive National Health and Nutrition Examination Survey (NHANES) data that included a more diverse population and children who were both bottle and breast fed, making them more suitable for use in the general population. Based off of these internationally recognized growth charts, childhood overweight is defined as a BMI-for-age between the 85<sup>th</sup> and 95<sup>th</sup> percentiles for children of the same age and sex in the baseline population, childhood obesity is defined as a BMI-for-age at or above the 95<sup>th</sup> percentile for children of the same age and sex in the baseline population, and extreme childhood obesity is thin

In recent years, public health professionals have implemented the social ecological model (SEM) of health promotion as a framework for childhood obesity prevention programs. The social ecological model recognizes the multiple levels of influence—namely interpersonal, institutions and organizations, community, and structure and systems—that effect an individual's health (Bronfenbrenner, 1994; Davison & Birch, 2001). Focusing on the "institutions and organizations" level of the SEM, schools have become a focal point for childhood overweight and obesity prevention

(Anderson & Butcher, 2006). To date, the effects of school based programs on weight status, specifically incidence and prevalence of obesity, are inconclusive (Brown & Summerbell, 2009; Sharma, 2006). Multiple reviews have demonstrated that school based childhood obesity programs can improve children's health behaviors, such as nutrition behaviors, physical activity, and television watching (Doak, Visscher, Renders, & Seidell, 2006; Katz, O'Connell, Njike, Yeh, & Nawaz, 2008; Sharma, 2006). Furthermore, some studies have even found a reduction in the incidence of overweight as a result of a school based intervention (Foster et al., 2008); however, other studies have found opposite results (Hung et al., 2015; Lubans et al., 2016; Luepker et al., 1996). The lack of consensus regarding the effectiveness of school based interventions for childhood obesity prevention underscores the importance of additional, scientifically rigorous, research regarding innovative school based programs.

### **Breakfast and Weight Status**

Numerous studies have demonstrated a positive relationship between breakfast skipping and overweight/obesity (Albertson et al., 2007; Berkey, Rockett, Gillman, Field, & Colditz, 2003; Deshmukh-Taskar et al., 2010; Niemeier, Raynor, Lloyd-Richardson, Rogers, & Wing, 2006; Sandercock, Voss, & Dye, 2010; So et al., 2011; Szajewska & Ruszczyński, 2010; Tin, Ho, Mak, Wan, & Lam, 2011; Utter, Scragg, Mhurchu, & Schaaf, 2007). NHANES data indicate that 20% of children aged 9-13 years old and 31.5% of adolescents aged 14-18 years old do not eat breakfast in the morning; these data also demonstrate that children and adolescents who skip breakfast have higher BMI-for-age z-scores and waist circumference than children and adolescent who eat breakfasts

(Deshmukh-Taskar et al., 2010). Similarly, in a 10-year longitudinal study of 2,371 girls, Albertson et al found that among girls who had higher BMI at baseline (9-10 years old), those who consumed breakfast more frequently were more likely to have a lower BMI at the end of the study (19 years old) (Albertson et al., 2007). Furthermore, using data from the Bogalusa Heart Study, researchers found that although children who skipped breakfast consumed significantly higher amounts of energy at lunch, than breakfast eaters, their total energy intake across the day was still lower (Nicklas, Bao, Webber, & Berenson, 1993). The mechanism by which breakfast skipping affects weight status is unclear. Some researchers speculate that the relationship is related to increased hunger later in the day and thus increased consumption (Niemeier et al., 2006); while others postulate that although breakfast skippers consume fewer calories throughout the day, they also are less physically active (Berkey et al., 2003). The issue of breakfast skipping is especially salient among urban populations, as studies have found that urban students are more than twice as likely to skip breakfast as suburban and rural students (Gross, Bronner, Welch, Dewberry-Moore, & Paige, 2004), and that breakfast skipping is consistent across urban students regardless of food security status (Dykstra et al., 2016).

In addition to children skipping breakfast, some studies have also reported the consumption of multiple breakfasts among school aged-children (Bailey-Davis et al., 2013; Lawman et al., 2014). In a study of 651 4<sup>th</sup>-6<sup>th</sup> grade low-income urban youth, researchers found that while 12.4% of children did not eat breakfast and 49.8% ate one breakfast, 25.5% of children ate two breakfasts and 12.3% of children ate three or more breakfasts (Lawman et al., 2014). Not only does this study corroborate previous studies

which reported higher BMI among breakfast skipper, but it also observed higher mean BMI percentiles among children who consumed three or more breakfasts (Lawman et al., 2014).

Furthermore, although there is little data regarding the relationship between breakfast location and obesity risk, recent studies suggest that breakfast location, specifically school breakfast, may be associated with breakfast consumption habits (Lawman et al., 2014; Ritchie et al., 2015; Van Wye, Seoh, Adjoian, & Dowell, 2013). Using baseline data from this study, researchers found that children who ate exclusively at school were more likely to eat fruits/vegetables, less likely to eat at high solid fats and added sugars (SFAS) foods, and more likely to meet national School Breakfast Program nutritional requirements, than children who ate exclusively at home (Polonsky et al., 2015). These analyses also revealed significantly greater odds of SFAS consumption among children who purchased breakfast at the corner store (Polonsky et al., 2015). Additionally, previous studies have indicated that eating breakfast at school is associated with higher daily intakes of key nutrients as compared to eating breakfast at home (Nicklas et al., 1993; Nicklas, O'Neil, & Myers, 2004).

### **The School Breakfast Program**

Although results regarding the relationship between breakfast and weight status is mixed, due to the wide impact school based programs can have on children's health and academic outcomes, researchers and public health professionals continue to look at the school meals program as an ideal intervention point. Building of the growing evidence to suggest that breakfast consumption improves academic (Adolphus, Lawton, & Dye,

2013; Hoyland, Dye, & Lawton, 2009; Littlecott, Moore, Moore, Lyons, & Murphy, 2015; Meyers, Sampson, Weitzman, Rogers, & Kayne, 1989; Rampersaud, 2009) and nutritional outcomes (Nicklas et al., 1993; Nicklas et al., 2004) among youth, policymakers have sought to increase youth's breakfast consumption. One example of this increased attention on breakfast can be seen through recent pushes to expand the School Breakfast Program (SBP). Officially authorized by Congress in 1975, following a successful pilot program, SBP is part of the U.S. Department of Agriculture's (USDA) Food and Nutrition Service division (United States Department of Agriculture). Similar to the National School Lunch Program (NSLP), SBP seeks to provide children access to nutritious and free or reduced price meals during the school day. To qualify for free or reduced price meals, children must attend a school that participates in SBP, and come from families with incomes at or below 130% of the Federal poverty level for free meals, and between 130-185% of the Federal poverty level for reduced-price meals; children from families over 185% of the Federal poverty level may purchase meals at full price (United States Department of Agriculture, 2012).

As a result of recent efforts to encourage SBP participation, the proportion of National School Lunch Program (NSLP) schools that also participate in the SBP increased from 48.8% to 91.2% between the 1990-1991 and 2011-2012 academic years (Food Research Action Center, 2015), and now the SBP serves an average of 11.2 million children per day (Food Research Action Center, 2015). However, despite these improvements, as of the 2013-2014 academic year, only half (53.2%) of low-income NSLP participants participated in the SBP (Food Research Action Center, 2015). In

response to these relatively low SBP participation rates, as compared to NSLP, many districts across the country have begun to implement universal school breakfast programs (Food Research Action Center, 2013). Universal breakfast programs offer free breakfast to all students regardless of income. By eliminating the hurdle of identifying which students qualify for the free/reduced meal, universal breakfast programs allow for more flexibility in meal distribution (Bailey-Davis et al., 2013; Food Research Action Center, 2013). Because universal breakfast provides a free meal to all students, regardless of income, it allows for more delivery options than traditional cafeteria based breakfast. Many school districts with universal breakfast continue to serve breakfast in the cafeteria before the start of the school day. However, some school districts have begun piloting more innovative delivery systems, such as breakfast in the classroom (BIC) and “grab-n-go” carts (Bailey-Davis et al., 2013). Both BIC and “grab-n-go” carts offer breakfast to students at the start of the school day either directly in their classrooms (BIC) or in the hallways on their way to class (grab-n-go) (Bailey-Davis et al., 2013; Food Research Action Center, 2013). Such programs are seen as positive alternatives to the traditional school breakfast program, as they reduce stigma and increase accessibility (Bailey-Davis et al., 2013; Food Research Action Center, 2013; Reddan, Wahlstrom, & Reicks, 2002).

Some evidence suggests that universal breakfast programs are associated with increased SBP participation (Anzman-Frasca, Djang, Halmo, Dolan, & Economos, 2015; Crepinsek, Singh, Bernstein, & McLaughlin, 2006) and reduced breakfast skipping (Anzman-Frasca et al., 2015; Ritchie et al., 2015). In a randomized control trial of 153 schools across six school districts, researchers found that although SBP participation

increased 18 percentage points more in schools with universal versus non-universal schools, the likelihood of eating breakfast did not vary (Crepinsek et al., 2006). Despite the evidence regarding universal breakfast programs versus non-universal breakfast programs, to date, there is no consensus regarding the efficacy of BIC specifically. For example, a cross-sectional survey of 2,289 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> grade students from 16 New York City public schools, students who received BIC were significantly less likely to report skipping breakfast that morning than students who did not receive BIC (8.7% vs 15%,  $p < 0.001$ ), however these BIC students were also more likely to report eating foods from multiple locations (51.1% vs 30.0%,  $p < 0.001$ ) (Van Wye et al., 2013). To date, the majority of studies regarding breakfast and weight status have been observational in nature. There are no randomized control trials that systematically examine the effects a classroom breakfast program initiative has on children's weight status.

### **Current Study's Contribution to the Literature**

Building off of previous research, the following study aims to explore the effects of a multi-component SBP intervention on school-aged children's weight status. In an effort to increase participation in the SBP and improve children's health and academic performance, the USDA has promoted BIC (United States Department of Agriculture) and multiple city governments across the country have implemented BIC initiatives ("Breakfast in the Classroom," 2011a; "Breakfast in the Classroom," 2011b; "DC Healthy Schools Act," ; Houston Independent School District, 2012). However, there is little evidence regarding what effect a BIC initiative might have on students weight status. In a cross-sectional survey of 1,571 4<sup>th</sup> graders, researchers found that both BMI and the

amount of kilocalories consumed at breakfast were higher among students who were in schools with BIC versus schools without BIC (Baxter et al., 2010). While past research on the efficacy of BIC has used primarily observation or quasi-experimental data, this study seeks to examine the effects of BIC using a randomized control trial design. This study is the first of its kind to use a randomized control trial design to test the effects of a BIC initiative on incidence of overweight and obesity. Using longitudinal data collected in an urban public school district, we will examine differences in the combined incidence of overweight and obesity, incidence of obesity, combined prevalence of overweight and obesity, prevalence of obesity, and BMI-z scores across school conditions. We hypothesize that students in schools that receive the SBP intervention will experience lower incidences of overweight and obesity, as compared to control schools. Results from this study can be used to inform future policies focused on the SBP and more specifically BIC initiatives.

## **CHAPTER 2**

### **INTRODUCTION**

Regular breakfast consumption has beneficial effects on children's cognition, academic performance, and dietary quality (Adolphus et al., 2013; Hoyland et al., 2009; Littlecott et al., 2015; Meyers et al., 1989; Nicklas et al., 1993; Nicklas et al., 2004; Rampersaud, 2009). Regular breakfast consumption, as compared to breakfast skipping, has also been associated with healthier child weight status, (Albertson et al., 2007; Berkey et al., 2003; Deshmukh-Taskar et al., 2010; Lawman et al., 2014; Niemeier et al., 2006; Sandercock et al., 2010; So et al., 2011; Szajewska & Rusczyński, 2010; Tin et al., 2011; Utter et al., 2007), and lower BMI-for-age z-scores and waist circumference (Deshmukh-Taskar et al., 2010). Despite these positive benefits of regular breakfast consumption, 20% of grade school-aged children in the US report skipping breakfast (Deshmukh-Taskar et al., 2010).

Recognizing the benefits of regular breakfast consumption and the high prevalence of breakfast skipping, particularly among low-income children (Basch, 2011), in 1975 Congress authorized the School Breakfast Program (SBP) (United States Department of Agriculture, 2012), which provides children from low-income households access to a nutritious breakfast at free or reduced cost. Currently 11.2 million children participate in the SBP each day; however this is only approximately half of the number of children who participate in the National School Lunch Program (Food Research Action Center, 2015). To help ensure that children obtain the health and academic benefits of regular breakfast consumption, the USDA encourages alternative methods of

implementing SBP, including offering breakfast in the classroom (BIC), in which all students are provided a free breakfast at the start of the school day in their classroom rather than before school in the cafeteria. BIC has been rapidly adopted by school districts across the country, including several of the country's largest urban school districts such as Philadelphia, Detroit, and Los Angeles ("Breakfast in the Classroom," 2011a; "Breakfast in the Classroom," 2011b; "DC Healthy Schools Act," ; Houston Independent School District, 2012). BIC has a demonstrated effect on participation in the SBP; BIC increases SBP participation two to three-fold and reduces the proportion of students skipping breakfast by increasing access and minimizing the stigma associated with participation in the SBP (Butcher-Powell, Bordi, Borja, Cranage, & Cole, 2003).

While BIC increases SBP participation, it is less clear whether BIC has a positive, neutral, or negative impact on children's weight status. As previous research has demonstrated, regular breakfast consumption is related to lower BMI, increasing the frequency of breakfast consumption through BIC may lower children's obesity risk.(Albertson et al., 2007; Berkey et al., 2003) Alternatively, offering all children BIC when some may have already eaten before arriving at school may promote excess consumption. This lack of clarity regarding the potential effect of BIC on childhood obesity has led to hesitation to implement, and reversal of BIC policies, in some localities.(Van Wye et al., 2013) Only one study to date has examined body weight outcomes related to BIC implementation. In a quasi-experimental study of BIC implementation in New York City, students offered BIC were more likely to consume breakfast foods from multiple locations than students without access to BIC, suggesting

that the school breakfast consumed in the classroom is being added to, rather than replacing, breakfast foods from other places (Van Wye et al., 2013). However, there was no increase in BMI or obesity prevalence associated with New York City BIC implementation (Corcoran, Elbel, & Schwartz, 2016).

Given the limited available information regarding the effect of BIC on children's obesity risk, the goal of this study was to determine the effect of a BIC initiative on weight outcomes among urban, low-income, school-aged children utilizing a group randomized trial study design. The BIC initiative combined offering BIC with a nutrition education curriculum that focused on eating one healthy breakfast, as well as social marketing in the schools and local corner stores, and parent outreach. We hypothesized that students in schools randomized to implement the BIC initiative would experience lower incidence of overweight and obesity, as compared to students in schools assigned to the control condition, in which universal breakfast was offered in the cafeteria prior to the beginning of the school day. This hypothesis was based on the belief that the BIC initiative would reduce breakfast skipping and encourage intake of the SBP as a replacement for less healthful breakfast options from other locations.

## CHAPTER 3

### MATERIALS AND METHODS

#### Design and Sample

A three-year randomized controlled trial was conducted in 16 Philadelphia K-8 public schools; the intervention lasted for 2.5 years. Participants were 4<sup>th</sup>-6<sup>th</sup> grade students at baseline. Due to the high proportion of students eligible for free or reduced-price meals, the School District of Philadelphia has a universal breakfast policy which provides SBP to all students free of charge, regardless of income. (Food Research Action Center, 2013) The 16 schools were evenly randomized to one of two conditions: 1) BIC at the start of the school day with a supplemental education and social marketing program known as “One Healthy Breakfast” and 2) breakfast offered in the cafeteria before the beginning of the school day (control) without any additional educational activities. The primary study outcome was incidence of overweight and obesity, while secondary outcomes included prevalence of overweight and obesity, incidence and prevalence of obesity, and BMI-z scores. SBP participation data from the school district were evaluated as indicator of the intervention’s implementation.

Schools were eligible for participation in the study if they met the following inclusion criteria: 1) at least 50% of students qualified for free/reduced priced meals through the National School Lunch Program (NSLP) based on family incomes at or below 130% of the Federal poverty level for free meals, and between 130-185% of the Federal poverty level for reduced-price meals (United States Department of Agriculture) 2), no existing BIC program or were willing to not offer BIC for the duration of the study

if randomized to the control condition, and 3) received SNAP-Ed nutrition education programming as part of the USDA's Supplemental Nutrition Assistance Program. This requirement was necessary since the education component of the intervention complemented existing SNAP-Ed programming. Students in special education classrooms were not included in the sample due to the presence of developmental or behavioral disorders that may have affected their ability to understand and/or complete the study measures.

Of the seventy-four eligible schools, twenty-five were chosen at random and invited to participate; nine of the invited schools declined due to unwillingness to accept randomization. The remaining 16 eligible and participating schools were similar to other schools in the School District of Philadelphia with respect to the percent of students of minority race/ethnicity, student enrollment, and percent of students qualifying for free and reduced price school meals (School District of Philadelphia, 2013). The mean  $\pm$  SD percent eligibility for free- or reduced-price meals among the 16 schools at the time of school recruitment (Spring 2013) was  $89.7 \pm 6.34\%$ . Prior to randomization, schools were matched into 8 pairs based on student enrollment, the schools' composition or racial/ethnic minority students, and food service type (full service cafeteria versus satellite cafeteria). Researchers conducted within-pair randomization using a random number generator in the spring of 2013 and school administrators were notified of their schools' condition assignment shortly after.

The 16 enrolled schools received \$1000 each for participating. Recruitment of students, parental consent, and student assent occurred in September 2013. Baseline data

were obtained after randomization by un-blinded trained research staff during the fall semester (October to December 2013). Schools randomized to the intervention condition began the intervention in January 2014. The intervention continued for 2.5 school years until June 2016. Midpoint data were collected in the spring of 2015 (May-June 2015) and endpoint data in the spring of 2016 (May-June 2016). The study was approved by and conducted in accordance with the ethical standards of the Office of Research and Evaluation at the School District of Philadelphia and the Institutional Review Board at Temple University.

Research staff visited each classroom in fall 2013 to explain the study and distribute parental consent and child assent forms; interested students returned their forms to research staff the next day in school. Students did not receive compensation for their participation. During all data collection periods, students completed measures in the classroom during the morning, after school breakfast was offered and prior to students' scheduled lunches.

Among the 2,715 eligible students, active parental consent and child assent were obtained for 1,463 students (53.9%). From that sample, 91 students were removed from the analytic sample (42 transferred schools before data collection, 31 were offered BIC during the baseline data collection period, 10 were in a special education classroom and determined to be unable to complete the survey measures, 4 had incomplete height and/or weight measurements, 1 was chronically absent, and 1 was missing survey data), yielding a total baseline sample of 1,371 students. Student enrollment in the study did not differ between intervention (n=645, 47.0%) and control (n=726, 53.0%) conditions. Students

had a mean age of  $10.8 \pm 0.96$  years. Approximately half of the sample (51.3%) was female, two-thirds (66.5%) was Black, and 39% was overweight or obese. There were no differences in baseline sample characteristics by study condition.

Over the 2.5-year intervention, there was no attrition at the school level. Among the baseline sample of 1,371 students, 78% (n=978) completed measures at midpoint, and 57.8% (n=793) at endpoint. Attrition rates did not vary between intervention and control schools at midpoint (68.5% vs 75.1%) or endpoint (55.2% vs 60.9%). Reasons for student attrition at each time point are described in Figure 1. Student transfer to a new school that was not part of the study (n=585) accounted for 97% of total attrition (n=602). Compared to Black students, Asian and White students were more likely to not remain in the study sample between baseline and midpoint (Asian: coef=1.17  $p<0.001$ ; White: coef=1.12  $p<0.001$ ); Asian students were more likely than Black students to not remain in the study sample between midpoint and endpoint (coef=1.50  $p=0.03$ ).

### **Intervention – The One Healthy Breakfast Program**

The school-based intervention, known as the One Healthy Breakfast Program included: 1) BIC, 2) nutrition-education, 3) social marketing, 4) corner store marketing, and 5) parent outreach. The One Healthy Breakfast Program was developed and delivered by The Food Trust, a community-based nutrition organization. The 8 intervention schools received the One Healthy Breakfast Program beginning in January 2014; the 8 control schools continued with cafeteria breakfast and received no additional nutrition education, corner store and social marketing programming, nor parent outreach.

*BIC:* As part of the universal breakfast program, all 4<sup>th</sup>-6<sup>th</sup> grade students in the intervention schools (n=8) were offered breakfast every morning in their classrooms at the start of the school day. The breakfast foods offered were part of the SBP; both the intervention and control schools received the same menus for breakfast regardless of breakfast service location (classroom vs. cafeteria).

*Nutrition Education:* Students in the intervention schools received 18, one-hour nutrition education lessons regarding the importance of eating one healthy breakfast a day over the course of the 2.5 years of intervention. These lessons were taught by a trained staff member from The Food Trust and were in addition to the students' regular nutrition education programming. The regular nutrition education continued in the control schools. Lessons included such topics as "What is a HEALTHY Breakfast?", "Rethink Your Drink", and "Influence of Advertising." Each lesson also included a nutrition education challenge that reinforced the materials taught for which students received prizes for participation.

*Social Marketing:* Students and staff received a variety of items, including folders, pens and lanyards with the One Healthy Breakfast logo; teachers and staff also received posters for the classrooms. All students attended an annual kick off educational assembly that reinforced One Healthy Breakfast themes. Students also engaged in school youth groups which were charged with planning 1-2 breakfast-focused events per year.

*Corner Store Marketing:* Prior research in Philadelphia has demonstrated that school-aged children frequently purchase energy-dense foods and drinks, such as soft drinks and chips, from corner stores for breakfast before school.(Lawman et al., 2014;

Lent et al., 2015) Shelf talkers encouraging shoppers to make healthy choices (i.e. water, 100% fruit juice, fruits and vegetables, whole grains, and low-fat dairy) were placed at 14 corner stores located <0.5 miles from the intervention schools (approximately 1-2 stores per school). Shelf-takers each included one targeted message (e.g. “Be SMART. Choose low-fat dairy” and “Be SMART. Choose water, 100% juice, or low-fat milk”) along with the One Healthy Breakfast mascot and logo.

*Parent Outreach:* Monthly newsletters were sent home with students; there were 24 newsletters total over the course of the study. The newsletters contained articles about breakfast, fun family activities, as well as the monthly school breakfast menu. Study staff also set up booths at Back to School Night and Report Card Conferences in order to further engage parents in the program.

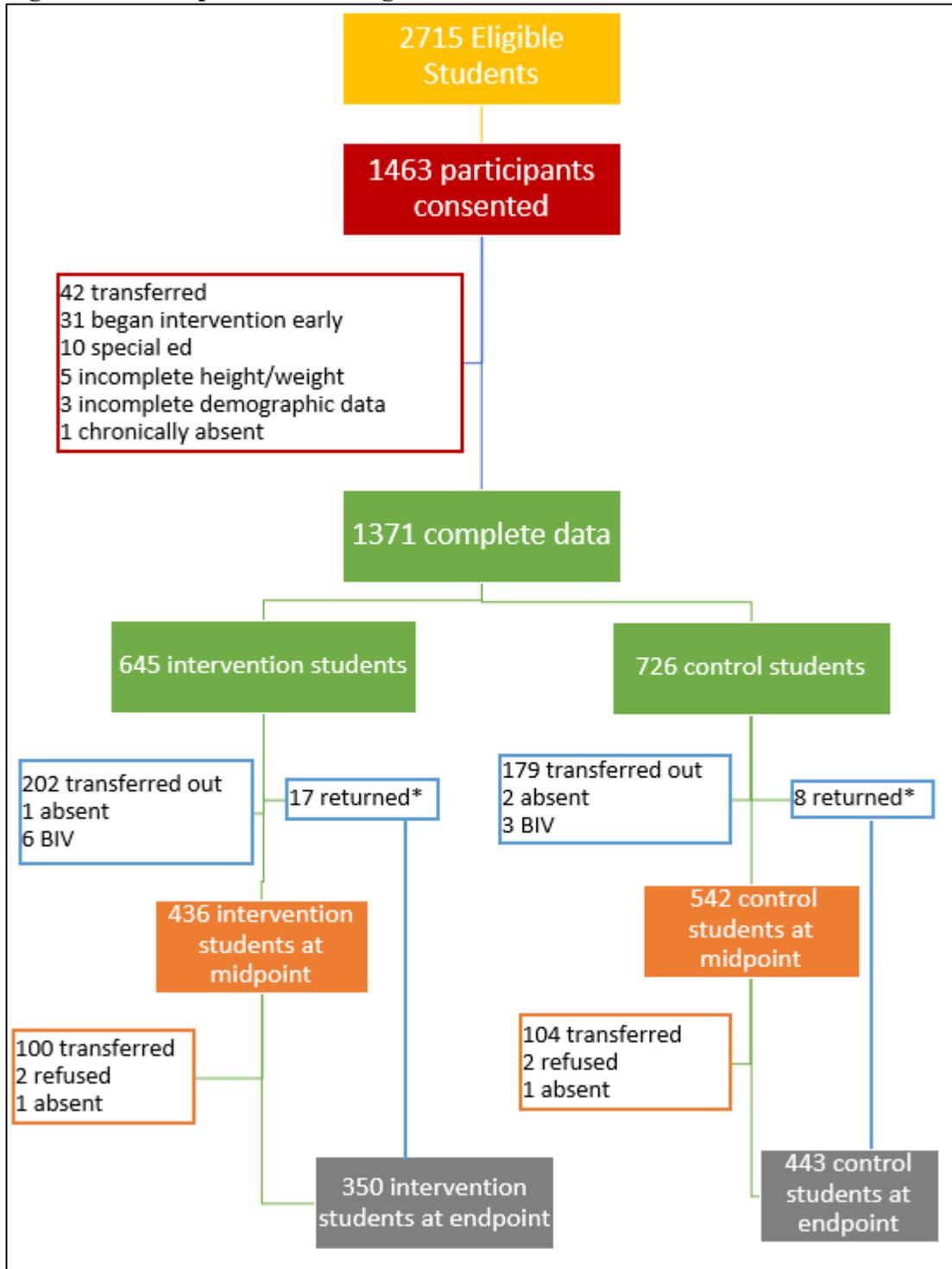
Greater detail about the One Healthy Breakfast program is available at [www.thefoodtrust.org](http://www.thefoodtrust.org).

### **Main Outcomes and Measures**

*Weight and Height.* Height and weight measurements were taken at all three time points by trained research staff using standard protocols. Two measurements of height (kg) and weight (cm) were obtained at each time point with portable stadiometers (SECA 217, Seca GmbH, Germany) and scales (SECA 869, Seca GmbH, Germany), respectively. Children were instructed to remove shoes, any extra layers of clothing, and all items from pockets for measures. If the two measures for height and weight differed by more than 1.0 cm and 0.2 kg, respectively, a third measure was taken and the two within the specified range were averaged. Inflexible hairstyles (e.g., braids) were

measured and subtracted from overall height. Body Mass Index (BMI) z-scores and percentiles based on age and gender were calculated for each student based on CDC 2000 reference data.(Kuczmarski et al., 2002) Weight status category was defined based on BMI-for-age percentile: underweight (<5<sup>th</sup> percentile); healthy weight ( $\geq$ 5<sup>th</sup> and <85<sup>th</sup> percentile); overweight ( $\geq$ 85<sup>th</sup> and < 95<sup>th</sup> percentile); and obese ( $\geq$  100% to  $\leq$  120% of the 95<sup>th</sup> percentile) (Flegal et al., 2009; Kuczmarski et al., 2002). Children's height and weight measurements were excluded if there were biologically implausible height and weight changes. Biologically implausible height and weight changes were defined as: 1) weight change of greater than 22.7 kg/50 lbs per year (34.0 kg/75 lbs per 1.5 years) or 27.2 kg/60 lbs per year (40.82 kg/90 lbs per 1.5 years) for youth who were obese at baseline, 2) any height decrease, 3) height change greater than 2 standard deviations above the normative height velocity change (Lawman, Mallya, et al., 2015; Lawman, Ogden, et al., 2015). In total, 9 students were excluded for biologically implausible height and weight measurements (Figure 1).

**Figure 1: Participant flow through the trial**



*School Breakfast Program (SBP) Participation.* Dates students participated in the SBP were extracted once a month from school's Food Services database by the Project Director for the duration of the study. The proportion of days students participated in the SBP during the 2.5 year intervention was calculated by dividing the number of days students participated in the SBP by the number of days they were in attendance.

*Student-level Demographic Information.* Children's race/ethnicity, sex, date of birth, free or reduced price meal status, and grade level were obtained from the school district. Children's race/ethnicity, based on parent report, was categorized as Black, Hispanic, Caucasian, Asian, or Other. Demographic data were collected at baseline.

### **Data Analysis**

Stata/SE (StataCorp, 2015) was used for all statistical analyses. Descriptive statistics were used to examine student demographic characteristics, weight status, and breakfast consumption habits. Logistic regression models were used to describe baseline differences between conditions, as well as retention differences by child race/ethnicity, sex, weight status, free/reduced lunch status, and age by intervention condition. All analyses used clustered sandwich estimators to adjust for within-school clustering.

The primary study outcome was the combined incidence of overweight and obesity. Secondary outcomes included incidence of obesity, prevalence of overweight and obesity, prevalence of obesity, and BMI z-score. Differences in SBP participation by intervention condition was also examined. Generalized estimating equation (GEE) models with logit link function were used to evaluate intervention differences for incidence and prevalence variables. A GEE model was also used to test a post hoc

hypothesis of an intervention  $\times$  baseline BMI percentile interaction predicting odds of becoming obese at the midpoint and endpoint. Generalized estimating equation (GEE) models with bootstrapping were used to evaluate intervention differences for SBP participation rates. Given the differential attrition by race/ethnicity over follow-up, race/ethnicity was included as a covariate for all models.

Statistical Power was determined for the primary study outcome and endpoint based upon preliminary data to estimate incidence, recruitment/retention rates, and design effects. The number of schools was selected based upon expected students to be enrolled per school and anticipated intraclass correlation. Sample size was selected to provide expected power  $>0.8$  to detect a risk ratio of 0.7 with a baseline incidence of 30% using  $\alpha=0.05$ . We enrolled 16 schools (8 control and 8 intervention) with a goal of recruiting approximately 110 students per school (N=1760 students). We reached planned schools, however enrollment within the schools was lower than in the pilot study.

## CHAPTER 4

### RESULTS

#### Student Participation

Baseline sample characteristics can be found in Table 1. The sample was 51.3% female and 66.5% Black. Students were divided approximately equally across the three target grades (4<sup>th</sup> grade: 35.2%, 5<sup>th</sup> grade: 34.8%, 6<sup>th</sup> grade: 30.0%). Approximately 80% of students qualified for free/reduced price meals as defined by federal poverty guidelines. At baseline, 2.6% of students were underweight, 58.4% normal weight, 17.6% were overweight, and 21.4% had obesity.

	Total Sample (n=1371)		Intervention (n=645)		Control (n=726)		p-value <sup>1</sup>
	n	%	n	%	n	%	
Age (mean ± SD)	10.8 ± 0.96		10.8 ± 0.96		10.8 ± 0.96		0.77
SBP Participation Rates (median)	18.2		18.9		17.2		0.78
Sex							0.85
Male	667	48.7	316	49.0	351	48.4	
Female	704	51.3	329	51.0	375	51.6	
Race/Ethnicity							
Asian	85	6.2	35	5.4	50	6.9	0.81
Black	912	66.5	436	67.6	476	65.6	
Hispanic	235	17.1	125	19.4	110	15.2	0.80
White	100	7.3	28	4.3	72	9.9	0.46
Multi/other	39	2.8	21	3.3	18	2.5	0.68
Grade Level							
4 <sup>th</sup> grade	482	35.2	229	35.5	253	34.9	
5 <sup>th</sup> grade	477	34.8	224	34.7	253	34.9	0.88
6 <sup>th</sup> grade	412	30.0	192	29.8	220	30.3	0.72
Free/Reduced Meals (yes)	1082	78.9	509	78.9	573	78.9	0.99
Weight Status							
Underweight	35	2.6	20	3.1	15	2.1	0.24
Normal weight	801	58.4	384	59.5	417	57.4	
Overweight	242	17.6	106	16.4	136	18.7	0.29
Obese	293	21.4	135	20.9	158	21.8	0.59

<sup>1</sup>p-values are for comparisons between intervention and control groups at baseline

## **Weight Status**

The primary study outcome was the incidence of overweight and obesity. From baseline to the endpoint, there was no significant difference in the combined incidence of overweight at obesity between intervention (11.7%) and control (9.1%) schools (Table 2). The incidence of obesity alone, however, was higher in the intervention schools (9.3%, 11.7%) than in control schools (4.3%, 4.4%) between baseline and the midpoint and endpoint ( $p=0.16$ ,  $0.29$ ). The predicted odds of incident obesity over 2.5 years was 3 times higher in intervention schools than control schools (Table 2). Additional tests of the interaction effect between baseline BMI percentile and incidence of obesity indicated that the intervention was associated with a higher probability of incident obesity at the endpoint for children with BMIs above the 80<sup>th</sup> percentile at baseline (OR: 1.13, 95%CI: 1.04-1.24,  $p=0.006$ ). The prevalence of obesity at the endpoint was also higher in intervention schools (28.0%) than in control schools (21.2%) (Table 2). There was no difference between intervention and control schools in the combined prevalence of overweight and obesity or mean BMI-z score at the midpoint and endpoint.

**Table 2: Overweight and Obesity Outcomes at Midpoint and Endpoint**

	Baseline % (n)	Midpoint % (n) <sup>a</sup>	Endpoint % (n) <sup>a</sup>	Midpoint Odds Ratio (95%CI) <sup>b</sup>	p- value	Endpoint Odds Ratio (95%CI) <sup>b</sup>	p- value
<b>Primary Outcome</b>							
<i>Incidence of ov/ob<sup>c</sup></i>							
Intervention	(239)	9.3 (24)	11.7 (23)	1.47 (0.86-2.51)	0.16	1.39 (0.76-2.52)	0.29
Control	(293)	6.6 (21)	9.1 (23)				
<b>Secondary Outcomes</b>							
<i>Incidence of ob<sup>c</sup></i>							
Intervention	(133)	7.1 (24)	11.6 (31)	1.52 (1.01-2.30)	0.047	2.95 (1.54-5.64)	0.001
Control	(158)	4.3 (18)	4.4 (15)				
<i>Prevalence of ov/ob<sup>c</sup></i>							
Intervention	37.5 (239)	42.7 (186)	44.9 (157)	1.10 (0.83-1.45)	0.49	1.22 (0.98-1.53)	0.08
Control	40.6 (293)	39.7 (215)	40.4 (179)				
<i>Prevalence of ob<sup>d</sup></i>							
Intervention	20.8 (133)	25.2 (110)	28.0 (98)	1.06 (0.81-1.39)	0.67	1.41 (1.05-1.89)	0.02
Control	21.9 (158)	23.6 (128)	21.2 (94)				
<i>BMI-z (mean ± SD)</i>							
Intervention	0.58±1.15	0.68±1.13	0.76 ±1.14	-0.002 (-0.16-0.15) <sup>e</sup>	0.98	0.06 (-0.08-0.21) <sup>e</sup>	0.40
Control	0.65±1.13	0.69±1.13	0.70±1.09				

## SBP Participation

During the baseline semester, the median proportion of days students participated in the SBP was 18.8% in intervention schools and 17.2% in control schools. Students in the intervention schools had significantly higher participation rates between baseline and midpoint (intervention: 79.3%, control: 19.6%) and between midpoint and endpoint (intervention: 61.6% vs. controls: 14.8%) (Table 3).

	<b>Base line %</b>	<b>Mid %</b>	<b>End %</b>	<b>Mid Coef (95%CI)<sup>a</sup></b>	<b>p-value</b>	<b>End Coef (95%CI)<sup>a</sup></b>	<b>p-value</b>
Intervention	18.8	79.3	61.6	0.45 (0.35-0.56)	<0.001	0.33 (0.20-0.45)	<0.001
Control	17.2	19.6	14.8				

a Odds were clustered by school and adjusted for race/ethnicity

## **CHAPTER 5**

### **DISCUSSION**

The objective of the current study was to identify the effect of a BIC-based initiative on weight outcomes among a low-income, urban sample of school-aged children. While there were no effects of the BIC initiative on the combined incidence of overweight and obesity, the prevalence of overweight and obesity, or mean BMI z-score, after 2.5 years of intervention, the BIC initiative did cause an increase in the incidence and prevalence of obesity among students after 2.5 years. Overall, the results are counter to our hypothesis that BIC with complementary intervention components to promote intake of one healthy breakfast would lead to a lower incidence of overweight and obesity among students.

Increasing SBP participation may have benefits for students, such as improved academic outcomes and reduced rates of breakfast skipping. BIC is often encouraged as a means of increasing SBP participation, as advocates of BIC argue that many children lack the time and resources to eat breakfast at home or from traditional school-cafeteria breakfast programs, and believe that serving children breakfast in the classroom at the start of the school day reduces many of the barriers and stigma associated with participating in the SBP (United States Department of Agriculture). However, the results of this study demonstrate that BIC is not without unintended consequences. Our findings that exposure to our BIC initiative increased incident and prevalent obesity among students. Evidence from the prior studies suggest that BIC may contribute to greater consumption of breakfast foods (Ritchie et al., 2015; Van Wye et al., 2013) and eating at

multiple locations (Ritchie et al., 2015). In an observational study of New York City public school students, students who received BIC reported eating 95 more calories per morning than students who did not receive BIC (Van Wye et al., 2013). This extra consumption aligns with our study's findings that the incidence and prevalence of obesity were higher in schools that offered BIC. This overall effect was particularly pronounced in the subgroup of children who were at or above the 80<sup>th</sup> percentile for BMI at baseline. These data suggest that being offered additional food in the morning promotes excess intake without sufficient caloric compensation either through reduced intake before school or after consuming the school breakfast. Further, students with high BMI in particular may be more susceptible to the negative weight consequences of a BIC initiative, as demonstrated by the intervention's effect on obesity incidence and prevalence, but not the incidence and prevalence of overweight and obesity combined, as these students may have traits such as high food responsiveness or limited satiety responsiveness that make them more likely to consume foods offered to them through BIC whether or not they are hungry, as well as a limited ability to compensate for the higher calories consumed at breakfast.

This study has numerous strengths including its randomized control trial design, the use of study-staff measured height and weight, and relatively long-term implementation of the BIC initiative. Also, the significantly different rates of SBP participation in intervention schools versus control indicate the intervention was implemented successfully. Further, our use of a large, low-income urban study sample was a strength. BIC is an increasingly utilized mode of SBP implementation in large,

urban school districts, therefore it is essential to understand the impact of BIC among populations such as these. Our study findings however may therefore have limited generalizability to students in non-urban locations or populations of differing demographic characteristics.

## **CHAPTER 6**

### **CONCLUSIONS**

As evident from these results, promoting BIC is unlikely to prevent overweight and obesity, and thus reductions in childhood obesity should not be the rationale for promoting BIC as a means of implementing the SBP. BIC may be an effective tool to increase participation in the SBP among low-income children, however it also has unintended consequences on children's weight status. Alternative, SBP implementation models such as grab-n-go carts and offering a second chance breakfast may increase SBP participation but differently impact children's obesity risk, however further research is needed on these models. Future research is additionally needed to examine how the composition of meals served as part of the SBP affects students' intake and satiety, and whether altering meal composition, such as increasing the protein and/or fiber provided by meals (Kral, Bannon, Chittams, & Moore, 2016; Kranz, Brauchla, Campbell, Mattes, & Schwichtenberg, 2017), may lessen students' excessive intake of the meal or improve satiety so students are better able to compensate for their breakfast intake later in the day. The SBP has clear benefits on academic and cognitive outcomes,(Adolphus et al., 2013; Anzman-Frasca et al., 2015; Meyers et al., 1989) and may contribute to improved diet quality among students.(Condon, Crepinsek, & Fox, 2009; Ritchie et al., 2015) However, when developing SBP promotion programs, it is important to consider the potential for unintended consequences among children, including those who are at risk for obesity, and develop initiatives that balance the risk and benefits of SBP.

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## APPENDIX A

### TEMPLE UNIVERSITY CONTINUING REVIEW



Research Integrity & Compliance  
Student Faculty Center  
3340 N. Broad Street, Suite 304  
Philadelphia PA 19140

Institutional Review Board  
Phone: (215) 707-3390  
Fax: (215) 707-9100  
e-mail: [irb@temple.edu](mailto:irb@temple.edu)

#### Certification of Re-Approval for a Project Involving Human Subjects

Date: 03-Feb-2016

Protocol Number: 20452  
PI: FISHER, JENNIFER O.  
Review Type: EXPEDITED  
Approved On: 01-Feb-2016  
Approved From: 01-Mar-2016  
Approved To: 28-Feb-2017  
Committee: A1  
School/College: PUBLIC HEALTH (0900)  
Department: TUSM: CORE (04770)  
Project Title: School Breakfast Policy Initiative (SBPI) Pilot Study

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The IRB re-approved the protocol 20452.

If applicable to your study, you can access your IRB-approved, stamped consent document or consent script through eRA. Open the Attachments tab and open the stamped documents by clicking the View icon next to each document. The stamped documents are labeled as such.

Before an approval period ends, you must submit the Continuing Review form via the eRA module. Please note that though an item is submitted in eRA, it is not received in the IRB office until the principal investigator approves it. Consequently, please submit the Continuing Review form via the eRA module at least 60 days, and preferably 90 days, before the study's expiration date.

As a reminder, you are obligated to submit modification requests for all changes to any study; reportable new information using the Reportable New Information form; and renewal and closure forms. For the complete list of investigator responsibilities, please see the Policies and Procedures, the Investigator Manual, and other requirements found on the Temple University IRB website: <http://www.temple.edu/research/regaffairs/irb/index.html>

Please contact the IRB at (215) 707-3390 if you have any questions

## APPENDIX B

### CITI TRAINING CERTIFICATION

#### COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

##### COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS\*

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Heather Polonsky (ID: 1707253)
- **Institution Affiliation:** Temple University (ID: 926)
- **Institution Email:** heather.polonsky@temple.edu
- **Institution Unit:** Center for Obesity Research and Education
- **Phone:** 215-707-5320
  
- **Curriculum Group:** Human Research
- **Course Learner Group:** Social/Behavioral Research Course
- **Stage:** Stage 2 - Refresher Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.
  
- **Record ID:** 19675475
- **Completion Date:** 13-Jun-2016
- **Expiration Date:** 13-Jun-2018
- **Minimum Passing:** 75
- **Reported Score\*:** 75

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Temple University (ID: 1758)	13-Jun-2016	No Quiz
SBE Refresher 1 – Defining Research with Human Subjects (ID: 15029)	13-Jun-2016	2/2 (100%)
SBE Refresher 1 – Privacy and Confidentiality (ID: 15035)	13-Jun-2016	2/2 (100%)
SBE Refresher 1 – Assessing Risk (ID: 15034)	13-Jun-2016	2/2 (100%)
SBE Refresher 1 – Research with Children (ID: 15036)	13-Jun-2016	2/2 (100%)
SBE Refresher 1 – International Research (ID: 15028)	13-Jun-2016	1/2 (50%)
SBE Refresher 1 – History and Ethical Principles (ID: 936)	13-Jun-2016	1/2 (50%)
SBE Refresher 1 – Federal Regulations for Protecting Research Subjects (ID: 937)	13-Jun-2016	2/2 (100%)
SBE Refresher 1 – Informed Consent (ID: 938)	13-Jun-2016	0/2 (0%)
SBE Refresher 1 – Research with Prisoners (ID: 939)	13-Jun-2016	2/2 (100%)
SBE Refresher 1 – Research in Educational Settings (ID: 940)	13-Jun-2016	1/2 (50%)
SBE Refresher 1 – Instructions (ID: 943)	13-Jun-2016	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: [www.citiprogram.org/verify/?k750de514-8372-411e-90fc-f38ed14bc221-19675475](http://www.citiprogram.org/verify/?k750de514-8372-411e-90fc-f38ed14bc221-19675475)

Collaborative Institutional Training Initiative (CITI Program)  
Email: [support@citiprogram.org](mailto:support@citiprogram.org)