PROTOCOL SUMMARY

1. STUDY TITLE

School Breakfast Policy Initiative (SBPI) Study

2. OBJECTIVES

The primary research question of Phase I is to assess the feasibility and acceptability of implementing the School Breakfast Policy Initiative (SBPI) among 4th-6th grade children in 4 K-8 schools during the 2012-2013 school year.

Specific Aims:

1. To develop the School Breakfast Policy Initiative (SBPI) intervention within the context of USDA's SNAP Ed nutrition education programming and the National School Breakfast Program in the School District of Philadelphia.
2. To conduct a pilot feasibility study among 4 schools (2 intervention and 2 control) to assess feasibility and acceptability.

The primary research question of Phase II is to evaluate the effects of a school breakfast policy initiative (SBPI) on the incidence of overweight and obesity as well as breakfast patterns among 4th-6th grade children in 16 K-8 schools during the 2013-2014 through 2015-2016 school years.
Specific Aims:

1. To implement the School Breakfast Policy Initiative (SBPI) intervention within the context of USDA's SNAP Ed nutrition education programming and the National School Breakfast Program in the School District of Philadelphia.
2. To conduct a randomized controlled trial (RCT) among 16 schools (8 intervention and 8 control) to compare the incidence of overweight and obesity and eating one breakfast.

3. BACKGROUND

BACKGROUND AND SIGNIFICANCE

The need for prevention. More than a third of American children are overweight or obese (1) with higher rates among low-income and minority groups (2, 3). The School District of Philadelphia (SDP), recognizing the importance of breakfast on learning outcomes (4-7), includes School Breakfast Program (SBP) participation as a metric for a principal's performance evaluation. We propose to develop and evaluate a School Breakfast Policy Initiative (SBPI) that combines classroom feeding, in-school nutrition education, social marketing and parent outreach. Specifically, we will promote the benefits of eating one healthy breakfast a day. Classroom feeding is the preferred method to increase school breakfast participation. While classroom feeding boosts SBP participation by increasing access (8, 9) and minimizing the social cost associated with participation, the effects of increasing school breakfast are unknown.

RATIONALE

Breakfast patterns among low-income children. Despite policy efforts at the national, state and local levels to increase school breakfast consumption, the frequency of breakfast consumption outside of school is unknown. We recently collected data on breakfast patterns among 369 ethnically diverse 4th-8th graders in Philadelphia with a mean ± SD age of 12.5 ± 1.2 y. Students were from 7 K-8 public schools where 84.6 ± 7.4% of students were eligible for free or reduced price meals (10). The sample was 56.1% female and predominantly African American (51.2%) or Hispanic/Latino (13.8%). Based on measured weight and height, almost half (48%) were overweight (20.1%) or obese (27.9%). Using a Breakfast Patterns Survey (BPS) we developed in collaboration with colleagues at the New York City Department of Health, participants reported (in the morning before lunch) whether or not they had eaten or drunk anything that morning from: home; corner store/restaurant; school cafeteria or classroom.

Approximately 20% reported having no breakfast, 54.7% reported consuming one breakfast, and 25.6% reported consuming ≥ 2 breakfasts. The majority of students (59%) who ate breakfast reported eating breakfast at home, 18% purchased items for breakfast from a corner store, and 34.0% ate breakfast at school. These data suggest significant variability of breakfast consumption among low-income, ethnically diverse children. Policies to increase school breakfast consumption will likely have different effects on the 20% of children who are currently without breakfast compared to the 26% who have 2 or more breakfasts. Our proposed research will be the first to examine a school breakfast initiative on breakfast patterns (inside and outside of school) as well as BMI. These data suggest that our messages to children and parents will need to focus on having one healthy breakfast (school or home) rather than a general injunction to eat breakfast.

Barriers to breakfast participation. Recently, we used qualitative methods to understand the chasm between universal free access and 32% SBP participation in Philadelphia. A total of six focus groups were conducted with parents (n = 2) and students (n = 4). A total of 23 mothers and 23 students in grades six through eight participated. Oversleeping emerged as a common barrier to eating breakfast at home and may prompt consumption of convenience items, corner store shopping, or missing breakfast altogether when the student arrives too late for school breakfast. By this age, many students are independently responsible for preparing and eating breakfast. Students discussed eating two breakfasts a day across two settings- home, en route to school, and at school, reporting that the practice is prompted by hunger. Students may see the practice as a norm, but parents are not aware of the practice. All parents disagreed that their child eats between leaving home and arriving at school.

Parents want to receive school menus, to be more involved in breakfast decisions with their child, and students want input into menu planning and taste testing. Student involvement and empowerment may help to overcome the social cost associated with participation in the universal free school breakfast program, ultimately boosting participation. Parents reported that "life gets in the way" of offering regular breakfast at home, sleeping patterns, work schedules, and meeting the needs of multiple children simultaneously interfered with their child's breakfast consumption at home. Parents appreciate and value the school breakfast in helping to overcome economic and socio-cultural environmental challenges, but parents were unaware that their children interact with the physical environment by eating food from corner stores, street vendors, and restaurants on their way to school. These data provide critical information about the context of breakfast

consumption among low-income, urban families. We will utilize these data to effectively frame any messages in the SBPI.

4. ELIGIBILITY CRITERIA

In Phase I, participants will be 4th-6th grade Philadelphia public school students from 4 schools. In Phase II, participants will begin as 4th-6th grade Philadelphia public school students from 16 schools and will be followed until they are 6th-8th grade students. Eligible schools must: (1) be K-8 schools that have over 50% of students qualifying for free and reduced meals and (2) have no existing classroom breakfast feeding program. Eligible schools will be matched on school size, and principals will be approached in a pre-determined random order within each matched pair. Based on our previous research, few schools (2 of 12) declined participation in similar studies. Participating schools, both intervention and control, will receive $1,000 for study participation.

5. TREATMENT PLAN

Phase I

Study Population. In Phase I, participants will be elementary school students in grades 4-6 from four K-8 schools in the School District of Philadelphia. Our estimated total eligible sample for Phase I is 600-1200 students, based on total enrollment of the schools, using an average of 25 students per class and 2-6 classes per grade, for 3 grades. This yields about 150-450 students at each school. Thirty schools meet the eligibility criteria, with enrollments ranging from 305 students to 1200 students.

Phase I includes developing the School Breakfast Policy Initiative (SBPI); determining school eligibility; recruiting the four pilot schools; conducting informative focus groups in the spring of 2012 to prepare for the nutrition education and social marketing components of SBPI; conducting a 6-month pilot study in two intervention and two control schools to assess feasibility of the methods and acceptability of the intervention; and conducting a second set of focus groups will be conducted in the two intervention schools following the 6-month intervention in the spring of 2013; 2 groups with students and/or parents and 2 groups with teachers.

Consent/assent and HIPAA forms will be collected when the 2012-2013 school year begins in Sept/Oct. Baseline measures, including height and weight, questionnaires (one page breakfast surveyand one page hunger scale), and demographic info (age, grade, birth date, gender and race/ethnicity) will be collected at all four schools once during the fall of 2012. A second set of focus groups will be conducted in the two intervention schools following the 6-month intervention in the spring of 2013; 2 groups with students and 2 groups with parents.

The SBPI program components (nutrition education, classroom feeding, social marketing, parent outreach) will begin in the two intervention schools after baseline measures are complete and will continue for six months. Follow-up measures (height/weight, breakfast questionnaire, food security questionnaire, hunger scale, and school characteristics and school performance measures) will be collected once during the spring of 2013.

All children in the four pilot schools (grades 4-6) will have their height and weight measured and provided to the school nurse for reporting to the state, but only consented/assented children will complete the questionnaires. The study measurements are estimated to take about 30 minutes for each consented/assented child to complete and will be limited to a portion of one class and will be scheduled to avoid core curriculum class times and at the school's convenience.

The estimated total focus group sample, for the focus groups conducted prior to and post-intervention, is 80 participants; 40 students from the 4^{th}-8^{th} grades and 40 parents/guardians with children in the 4^{th}-8^{th} grades, from eligible schools. Eight focus groups will be held; 4 with students and 4 with parents; with a maximum of 10 participants per group. Previous experiences have shown that approximately 30-50% of participants recruited and consented prior to the focus groups do not attend the focus groups, therefore, we will recruit 15-20 participants per group (total recruited sample of 160), with an expected consent and show rate of 8-10 participants per group (total focus group sample of 80). Only participants who have returned consent/assent will be included in the focus groups; parental consent/child assent for the student focus groups, and adults consent for the parent focus groups. Participants will be a self-selected convenience sample, with access to the focus groups granted on a first-come first-serve basis as consents/assents are returned. Focus groups will be held in the school building the participants were recruited from, last approximately 60 minutes, and be scheduled to avoid core curriculum class times and at the school's convenience.

Phase I will also include a parent component. The parent component of the SBPI study will ask parents to complete a questionnaire about their families' eating habits. The estimated total sample for parent component in Phase I is 237-546 participants, based on the total student enrollment of the pilot study, assuming approximately 70% of enrolled students agree to participate in Phase I and 65% of consented students' parents will return the consent form and Core Food Security Module (CFSM). The CFSM will be sent to the parents of study participants in the Spring of 2013 and parents will have the option of mailing the completed consent form and CFSM to the study coordinator or sending it back to school with their child. Preliminary analysis will begin once collected data has been entered and cleaned, during the summer and fall of 2013. The purpose of Phase I is to evaluate the feasibility and acceptability of the SBPI. Based on the data obtained in this small pilot, Phase I will also consist of refining the intervention and research materials for full implementation in the future.

Phase II

Study Population. In Phase II, participants will begin as 4^{th}-6^{th} grade Philadelphia public school students from 16 K-8 schools in the School District of Philadelphia, and will be followed until they are 6^{th}-8^{th} grade students. Our estimated total eligible sample is 2400-6000 students, based on total enrollment of the schools, using an average of 25 students per class and 2-6 classes per grade, for 3 grades. This yields about 150-450 students at each school. Sixty six schools meet the eligibility criteria, with enrollments ranging from 305 students to 1200 students.

Phase II will consist of a three year RCT in eight intervention and eight control schools to evaluate the effects of a school breakfast policy initiative (SBPI) on the incidence of overweight and obesity as well as breakfast patterns. Consent/assent and HIPAA forms will be collected when the 2013-2014 school year begins in Sept/Oct. Baseline measures, including height and weight, questionnaires (one page breakfast survey and one page hunger scale), and demographic info

(age, grade, birth date, gender and race/ethnicity) will be collected at all sixteen schools once during the fall of 2013. Two sets of focus groups will be conducted in the eight intervention schools. The first set of focus groups will be conducted midway through the intervention in the spring of 2015 and the second set of focus groups will be conducted at the end of the intervention in the spring of 2016. Both sets of focus groups will consist of 16 groups: 8 groups with students and/or parents and 8 groups with teachers. The SBPI program components (nutrition education, classroom feeding, social marketing, parent outreach) will begin in the eight intervention schools after baseline measures are complete and will continue for three years. Follow-up measures (height/weight, breakfast questionnaire, hunger scale, and school characteristics and school performance measures) will be collected midway through the study in the spring of 2015 and at the end of the study in the spring of 2016.

All children in the sixteen schools (grades 4-6 in the 2013-2014 school, grades 5-7 in the 2014-2015 school year, and grades 6-8 in the 2015-2016 school year) will have their height and weight measured and provided to the school nurse for reporting to the state, but only consented/assented children will complete the questionnaires. The study measurements are estimated to take about 30 minutes for each consented/assented child to complete and will be limited to a portion of one class and will be scheduled to avoid core curriculum class times and at the school's convenience.

The estimated total focus group sample, for the focus groups conducted during and after the intervention, is 160 participants; 80 students and/or parents from the 4^{th}-8^{th} grades and 80 4^{th}-8^{th} grade teachers from eligible schools. Sixteen focus groups will be held; 8 with students and/or parents and 8 with teachers; with a maximum of 10 participants per group. Previous experiences have shown that approximately 30-50% of participants recruited and consented prior to the focus groups do not attend the focus groups, therefore, we will recruit 15-20 participants per group (total recruited sample of 160), with an expected consent and show rate of 8-10 participants per group (total focus group sample of 80). Only participants who have returned consent/assent will be included in the focus groups; parental consent/child assent for the student focus groups, and adults consent for the teacher and parent focus groups. Participants will be a self-selected convenience sample, with access to the focus groups granted on a first-come first-serve basis as consents/assents are returned. Focus groups will be held in the school building the participants were recruited from, last approximately 60 minutes, and be scheduled to avoid core curriculum class times and at the school's convenience.

Phase II will also include a parent component. The parent component of the SBPI study will ask parents to complete a questionnaire about their families' eating habits. The estimated total sample for parent component is 1090-2730 participants, based on the total student enrollment of the study, assuming approximately 70% of enrolled students agree to participate in the main study and 65% of consented students' parents will return the consent form and Core Food Security Module (CFSM). The CFSM will be sent to the parents of study participants in the Fall of 2013 and Spring of 2014 and parents will have the option of mailing the completed consent form and CFSM to the study coordinator or sending it back to school with their child.

Preliminary analysis will begin once collected data has been entered and cleaned, during the summer and fall of 2015.

RANDOMIZATION

Schools will be assigned to either the control or intervention arm of the study by random assignment using a computer generated numbering system to assure randomization is not biased.

Intervention Arm. The School Breakfast Policy Initiative (SBPI) seeks to increase participation in the school breakfast program. In Phase I, two intervention schools will receive an intervention that includes elements of the four strategies below to increase breakfast participation and the intervention would be tailored based on principal and school feedback. In Phase II eight intervention schools will received an intervention that includes elements of the four strategies below to increase breakfast participation and the intervention would be tailored based on principal and school feedback.

1. **Classroom feeding:** Providing breakfast in the classroom at the start of the school day is much less expensive since it can be done without costly carts, students can help deliver the breakfast to classrooms, or a single food service staff person can make one round of classroom drop-offs. Hence, classroom feeding has become the method of choice to increase breakfast participation in school districts. Large urban school districts such as New York are expanding their classroom feeding programs and Pennsylvania supports this practice by recognizing classroom breakfast as instructional time.
2. **Nutrition education:** Nutrition lessons and related activities (e.g., taste testing, cooking events) will be provided to create practical knowledge and skills for healthy eating. Choosing one healthy breakfast will be a focus of the nutrition education and will be provided within the context of Philadelphia's EAT.RIGHT.NOW. SNAP-Ed Program.
3. **Social marketing:** A social marketing campaign will be designed to promote consumption of one healthy breakfast a day and will display overarching messages and images through all school venues. The marketing will include a healthy breakfast points-based reward program designed by the students, promotional campaigns and youth leadership activities.
4. **Parent outreach:** SBPI will use a variety of communication methods to engage families and offer education that meets their needs, including interactive parent cooking and healthy eating workshops focused on breakfast, school breakfast menus, parent newsletters and information tables at parent-teacher meetings.

Control Arm. Control school activities include height/weight, demographic, and questionnaire data collection. No 'placebo' intervention is delivered. Control schools offer and promote breakfast as they normally do during the school year.

CONSENT

Students and Parents. Parental consent and student assent will be obtained prior to any study procedures as outlined. Parent consent and student assent includes permission for the study group to collect height and weight, demographic information (including age, gender, birth date, grade and race/ethnicity), and questionnaire data from each child. It also includes permission for the study group to collect meal participation data on each consented student. Additionally, parent consent will be obtained for the parent component, and parent and teacher consent and student assent will be obtained for the focus groups.

Parental consent/student assent forms for the study will be sent home with students for review and signature. Completed forms will be returned in school to the study team by students and collected in 4-6th grade classrooms of consented schools. Study staff will coordinate with teachers for several 15-minute info sessions to explain the study components, consent/assent form and to collect completed forms. Explanation of the study will include that participation is completely voluntary, with no penalty for not participating and that signatures are required for

each student and one parent or guardian. During Phase I, it will also be explained that only two schools (of four) will receive the intervention and the other schools will only participate in the measures (height, weight, breakfast questionnaire and demographics). During Phase II, it will be explained that only eight schools (of sixteen) will receive the intervention and the other schools will only participate in the measures (height, weight, breakfast questionnaire and demographics). Additionally, it will be explained that all students in intervention schools will be exposed to the same activities (classroom feeding, nutrition education, etc) regardless of whether they provided consent/assent or not. Lastly, it will be explained that if, even after turning in a completed consent/assent form, a student or parent/guardian changes their mind and does not want to participate, they can always withdraw consent/assent.

Focus group participants for the student groups will employ recruitment methods similar to those outlined above. Parental consent/student assent forms for the focus groups will be sent home with students for review and signature. Completed forms will be retuned in school to the study team by students and collected in the 4th-8th grade classrooms of eligible schools. Study staff will coordinate with teachers for sever 15-minute info sessions that explain the focus group components, consent/assent form, and to collect completed forms. Explanation of the focus group will include that participation is completely voluntary, with no penalty for not participating and that signatures are required for each student and one parent or guardian. It will also be explained that only the first 10 students to return their completed consent/assent forms will be granted access to the focus groups. It will also be explained that if, even after turning in a completed consent/assent form, a student or parent/guardian changes their mind and does not want to participate, they can always withdraw consent/assent. In addition to classroom presentations, focus group participants, both students and parents, will be recruited through the utilization of parent-teacher report card conferences, and through methods recommended by the principal (e.g., letter from the principal mailed home). For recruitment during teacher-parent conferences study staff will coordinate with the principal to set up a table in the eligible schools which parents and students can approach to hear a explanations of the focus group (the same explanation given during the classroom presentations), and complete consent/assent forms.

For the parent component, the Core Food Security Module (CFSM) will be sent to the parents of study participants in the Spring of 2013 in Phase I and in the Fall of 2013 and Spring of 2014 in Phase II. Parents will have the option of mailing the completed consent form and CFSM to the study coordinator or sending it back to school with their child. Parents who complete the CFSM will be mailed a $5.00 grocery gift card in the mail as a thank you for participation.

Principals. School principals will consent to have their school participate in the study intervention or control groups. During Phase I, every child in 4-6th grade will be exposed to the study intervention if their school is randomized to the intervention arm. During Phase II, every child in 4-6th grade in the 2013-2014 academic year, 5-7th grade in the 2014-2015 academic year, and 6-8th in the 2015-2016 academic year will be exposed to the study intervention if their school is randomized to the intervention arm. Principals will also consent to allow us to collect school meal participation data and conduct focus groups prior to and post-intervention.

Confidentiality. Parental consent and student assent will be obtained to perform all study procedures as outlined and includes permission to collect demographic information (gender,

grade, age, birth date and race/ethnicity), height and weight, and questionnaire data from each child,. It also includes permission to collect meal participation data. HIPAA forms will also be collected to protect the student's private health information. Parental consent and student assent will be obtained to perform all focus group procedures as outline and includes permission to tape record focus group discussions and collect demographic questionnaires from focus group participants. Additional procedures will be taken to protect student's confidentiality. Measures will be taken in a private space with clothes on. No identifying information, including students' and parents' names, will be used or said during the focus group discussions and will not be written on the focus group demographic survey. All staff will be trained and have acquired Act 33 clearance to work with children. All child records will be kept as safe and as private as possible, labeled by an ID number, not the child's name. The child's name will be linked to the number only on a separate log. Hard copies of data will be stored at Temple University (TU), in a locked file drawer of the Project Coordinator. Electronic records will be stored on a HIPAA-protected TU server. The focus groups will be tape recorded and the words that participants say will be typed out, but participants will never be identified by name, and the typed copy will be kept in a locked file. The typed copy will be reviewed and analyzed by Temple staff. Tapes will be destroyed after the information on them is extracted. The focus group demographic questionnaire will not have participants' name on it and the information will be used for descriptive purposes only, no participant will be individually identified. The completed questionnaires will be kept in a locked file. The only people who will have access to the focus group information are the study investigators. All staff will be trained to meet ethical, research, and privacy standards and will complete the web-based research compliance courseware (CITI) training program.

METHODS

Height and Weight. Height/weight measures will be obtained privately by study staff members in a private space (nurse's office) at each school. As we have done in previous and ongoing school-based interventions, this data will be provided to the school nurse (in all schools) for reporting to the state. Weight will be measured using a balance beam scale and height by a stadiometer with subjects dressed in light indoor clothing and without shoes. During Phase I each of the 4 schools will use the same scale and stadiometer to prevent measurement error. During Phase II each of the 16 schools will use the same scale and stadiometer to prevent measurement error. *See attached data collection form.*

Food Service Data. Student meal participation in federal meal programs will be obtained electronically from the Food Service Department reporting system. Food Production Records will be photocopied and collected by study staff from each school to determine what foods were offered and served to students. Food service data will be collected monthly.

Demographic information. Gender grade, age, birth date, and race/ethnicity will be obtained on consented children participating in the SBPI study. Study staff will receive this information from the School District of Philadelphia at the time of height/weight collections. If the district is unable to provide this information, it will be obtained from the student or school. *See attached data collection form.*

Breakfast Questionnaire. This short, 1-page questionnaire was designed to help us understand the breakfast eating patterns of students. *See attached data collection form.*

Hunger scale. This short, 1-page questionnaire was designed to help us understand the breakfast eating patterns of students and the commuting patterns of the students. *See attached data collection form.*

School Characteristics Measure. This 2-page questionnaire was designed to help us understand the culture of our schools, including the meal schedules, enrollment, demographic breakdown, and personnel changes. *See attached data collection form.*

School Food Environment Survey. The purpose of the school food environment survey is to understand 1. opportunities that students have for eating in the morning at school, and 2. activities currently being conducted at the school that promote breakfast. The survey will be implemented via interview with school principals and/or other key personnel who are knowledgeable about the school food environment. This survey will be collected each year at the time of data collection.

School Performance Measure. This 3-page questionnaire was designed to help us understand the culture of our schools, including overall academic performance, absences, and disciplinary actions. *See attached data collection form.*

Core Food Security Module. This short, 1-page questionnaire was designed to help us understand students' food security status via parent report. *See attached data collection form.*

Student and Parent Focus groups. Qualitative data will be obtained by Temple study staff from a small sub-sample of consented/assented students and parents in eligible schools. During Phase I eight focus groups will be conducted; 4 with students in the 4^{th}-8^{th} grades, and 4 with parents/guardians with children in the 4^{th}-8^{th} grades. During Phase II sixteen focus groups will be conducted; 8 with students and/or parents in the 4^{th}-8^{th} grades, and 8 with 4^{th}-8^{th} grade teachers. As was done in previous studies, focus groups will be held in the schools that the participants were recruited from, in a space (empty classroom) and at a time (non-core curriculum) most appropriate and convenient for the school. Students,parents, and teachers will participate in ~55 minute discussions with other students and parents from their school, on the breakfast habits of families and the promoters and barriers to eating school breakfast. Focus groups will be conducted by Temple study staff, including one moderator and 1-2 note takers, and will be tape recorded. Participating students will receive a small snack and participating parents will receive a $25.00 gift card as a thank you for participation. During Phase I focus groups will be held in the spring of 2012 (n=4, 2 student groups and 2 parent groups) prior to the intervention and in the spring of 2013 (n=4, 2 student groups and 2 parent groups), post-intervention. During Phase II focus groups will be held in the spring of 2015 (n=16, 8 student and/or parent groups and 8 teacher groups) midway through the intervention and in the spring of 2016 (n=16, 8 student and/or groups and 8 teacher groups), post-intervention.

Student and/or Parent and Teacher Focus Group Demographic questionnaire. Immediately following the discussion portion of the focus groups, student, parent, and teacher participants

will be given a short, 6-9 item self-administered questionnaire designed to obtain basic demographic data, including age, gender, grade, and race/ethnicity.

6. RISKS

This study and the focus groups imposes minimal risks to participants. The research will be conducted at no cost to the participant, individual or the School District. All measures will be completed during non core curriculum time school hours. To avoid discomfort and protect privacy, the anthropometric measurements (height and weight) and demographic information will be collected and recorded in private behind a screen. The student does not need to disrobe. For all self-administered questionnaires and surveys, students are spaced apart; only the study identification number is recorded, and forms are collected directly by study staff. During the focus group discussions, individual's names will not used, instead participants will be given color name tags.

7. BENEFITS

Study participants achieve no direct benefit to participating in this research study or the focus groups; however, data collected from this study may help to identify sources of intervention for future studies addressing childhood obesity through school environments. There are potential health benefits to the parents and children from any changes to healthier lifestyle choices that might occur as a result of the study intervention. There are potential benefits for science and public health as well, as results from this study have the potential to make an important and substantial contribution to the education and health community in terms of understanding how to promote breakfast in schools.

During Phase I the participating schools and the School District will benefit by having research staff from TU measure heights and weights on all children in 4^{th}-6^{th} grades (600-1200 children) in the 4 enrolled schools in the fall of 2012 and the spring of 2013. During Phase II the participating schools and the School District will benefit by having research staff from TU measure heights and weights on all children in 4^{th}-6^{th} grades in the 2013-2014 academic year, 5^{th}-7^{th} grades in the 2014-2015 academic year, and 6^{th}-8^{th} grades in the 2015-2016 academic year (600-1200 children) in the 16 enrolled schools. The research staff will provide the data to the school nurses for reporting to the state.

8. ALTERNATIVE TREATMENT

The alternative is to not participate.

9. DATA COLLECTION AND STATISTICS

Analysis. Participants in the intervention and control schools will be compared on breakfast participation. We will use logistic regression to model participation (yes/no) following the intervention. Logistic regression will also be used to assess whether breakfast participation is associated with decreased odds in overweight/obesity status. We will analyze the demographic and breakfast patterns questionnaire data using descriptive statistics (i.e., means, standard deviations, frequencies, and percentages).

Intervention Effects. Schools represent a source of potential dependency; participants within a school (i.e., cluster) often share common selection factors or exposures, so that observations taken on participants from the same cluster are likely to be correlated (8). Any such correlation will violate the independence of errors assumption that underlies the familiar analytical methods based on the General Linear Model (GLM) (9). To account for the potential sources of correlation at the school level and any differences between schools, we will include school as a fixed effect variable in an analysis of covariance (ANCOVA) with baseline measure included as a covariate. Using this ANCOVA design, we will test the effect of the intervention relative to the control condition on changes in weight (pre-post).

By the nature of the small sample size (N = 4 schools) of Phase I, we recognize that we will be underpowered for definitive between-group conclusions; however, this study will provide the data necessary for powering larger studies and/or intervention enhancement. Specifically, we will obtain estimates of the effect size of the intervention as well as the intra-cluster correlation (correlation at the school level) to power a larger mixed model research design.

The primary outcome is incidence of overweight and obesity. Our previous research leads us to expect ≥30% reduction in incidence of overweight and obesity for the intervention group from a baseline rate of approximately 30% (i.e., incidence of 30% in control group and 21% in intervention group). Thus, our study needs to be able to detect a risk ratio of .7 with a baseline incidence of 30%. Assuming α=.05, Power ≥.80, and ICC≤.01, this translates into a minimum sample size of 15 schools for Phase II. We will enroll 16 schools (8 control and 8 intervention) to keep the arms equal and protect against attrition. We expect to recruit approximately 110 students per school yielding 1760 students in 16 schools or clusters.

10. MEDICAL RADIATION SUBCOMMITTEE/INSTITUTION BIOLOGIC COMMITTEE APPROVAL

Not applicable.

11. IND/IDE NUMBER; INVESTIGATIONAL DRUG DATA SHEET

Not Applicable.

12. REFERENCES

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