INTERVENTION TO REDUCE SUGAR INTAKE IN CHILDREN

Research Proposal: Intervention to Reduce Sugar Intake

and Improve Diet Quality in Children

Catherine M. Miosi, RDN, CD

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Mount Mary University

Janine M. Bamberger, MS, RDN, CD

Assistant Professor, Department of Dietetics

Dana Scheunemann, PhD, MS, RD, CD

Assistant Professor, Department of Dietetics

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Abstract

The average intake of added sugar was 17 teaspoons for children in 2017-2018 (USDA, 2020). This is 5 teaspoons more than the recommended limit of 12 teaspoons based off a 2000 calorie diet set by the Dietary Guidelines for Americans (DGA). This is concerning due to research that shows overconsumption of added sugars is associated with reduced diet quality and preventable diseases and ailments (Yang et al., 2014). While there are interventions that have been done to reduce sugar intake and improve the diet quality of children, relatively few studies have examined the effect of a comprehensive nutrition education program taught by dietitians to fourth grade students with familial/parental involvement. The purpose of this proposal is to recommend a study that evaluates the effectiveness of a nutrition program such as this in reducing sugar intake and increasing vegetable and fruit intake. It is hypothesized that children enrolled in the nutrition education program will consume significantly less added sugar and include a higher quantity of fruits and vegetables following the year-long program, in comparison to the control groups. A total of 620 fourth grade students from 12 different Milwaukee Public Schools will be included in the study. Anticipated results indicate the intervention group will significantly decrease their sugar intake and significantly increase their vegetable intake following the completion of the nutrition program at the end of the school year. The control group is not anticipated to have significant changes in dietary intake from the beginning of the school year to the end of the school year. A final discussion will include topics such as the strengths and limitations of the study as well as a comparison to other studies and suggestions for further studies.

Keywords: added sugar, diet quality, nutrition education program, preventable diseases

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Chapter 1: Introduction to the Study

The purpose of this document is to detail a study that will investigate the effectiveness of a nutrition education program delivered to elementary students at public schools. The program will consist of a bi-weekly nutrition educations classes led by a registered dietitian. Students in this program will also partake in nutrition-related activities and projects throughout the course of the schoolyear. Measures will be taken to create a health promoting environment at the participating schools and parent involvement will be encouraged with take-home activities. The goal of this program will be to improve the participants' nutrition knowledge, diet quality and health-related behaviors.

Background

Overconsumption of added sugars is associated with reduced diet quality, obesity, cardiovascular disease, diabetes, high blood pressure, mood disorders, dental caries and other preventable diseases and ailments in both children and adults (Yang et al., 2014). While the harmful effects of added sugar intake are well known, studies have found that most Americans consume more than the recommended limit set by the Dietary Guidelines for Americans (DGA). Drewnowski et al. found that the greatest source of added sugar in the diet of US children and adults was sugar-sweetened beverages, followed by grain desserts, fruit drinks, candy, and then dairy desserts (Drewnowski et al., 2014). According to the United States Department of Agriculture (USDA), in 2017-2018 the average daily intake of added sugars was 17 teaspoons for both children and adults (USDA, 2020). This is 41.7% more than the recommended limit of 12 teaspoons based off a 2000 calorie diet set by the DGA. Multiple health organizations propose that the recommended limit of calories consumed from added sugars should be even less than the 10% limit set by DGA, with World Health Organization (WHO) recommending lowering added sugar intake to 5% of total energy intake (WHO, 2015) and the American Heart Association (AHA) recommending lowering added sugar intake to 6% of total energy intake for further health benefits (AHA, 2022).

Health care organizations agree that sugar intake should be decreased by both children and adults, but the most effective time and intervention to target this change needs to be determined. Authors of a prospective cohort study found a strong association between sugarsweetened beverage intakes in early childhood and in later childhood (Ziesmann et al., 2019). Results of another prospective cohort study indicated that food behaviors established in childhood may significantly transpire into adulthood (Mikkilä et al., 2005). This research suggests that not only could health behaviors as a child have an impact on the health outcome as an adult, furthermore, establishing positive health behaviors and dietary patterns as a child may lead to a continuance of positive health behaviors as an adult. For this reason, targeting reduction of sugar intake in young children may allow for the largest impact on health outcome.

Problem Statement

While there have been studies on various nutrition education programs, relatively few studies have examined the effect of a comprehensive nutrition education program taught by dietitians to fourth grade students with familial/parental involvement.

Purpose of the Study

In this study, I will explore the difference in dietary intake between the students who participate in the nutrition education program and those who do not receive nutrition education.

Research Question:

The research question is: Will the nutrition education program have a significant impact on participant dietary intake of added sugar, fruits, and vegetables?

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Hypotheses

H_o: There will be no statistically significant difference in dietary intake between groups.

H_a: Children enrolled in the nutrition education program will consume significantly less added sugar and include a higher quantity of fruits and vegetables following the year-long program, in comparison to the control groups.

Nature of the Study

The study will be a randomized controlled trial. The study will take place in Milwaukee Wisconsin, within participating Milwaukee Public schools (MPS schools). The goal of the study will be to include at least twelve MPS schools with a minimum of 40 fourth grade students. Classrooms with students in the fourth grade will be randomly selected as control or intervention groups.

The intervention group will participate in a yearlong nutrition education program developed by based mostly off the Nutritious, Delicious, Wisconsin and Serving up MyPlate curriculum (Williams et al., 2022) (USDA, n.d). The curriculum will contain topics such as the importance of a nutritious diet, building a balanced plate, the function of macronutrients and micronutrients in our body, the importance of hydration and more. Please refer to Appendix A for further details on lesson contents and class schedule. Nutrition education will be delivered in 60-minute-long bi-weekly sessions by the registered dietitian to the intervention students. Students will be sent home with a printed summary of the lesson taught that week. They will be asked to review it with their parents and return a signed slip the following week indicating that this was completed, please see Appendix B for the form. Students will also be asked to complete at least one suggested activity provided by the program at home with their family each month and once again be asked to return a signed slip to show this is completed. Please refer to Appendix C for the list of suggested activities and Appendix D-H to see the activity sheets that will be provided. Refer to Appendix I to see the slip that must be signed to show completion of the activities.

Students in both the intervention and control groups will be asked to complete a set of 24hour diet recalls with the help of their parents prior to and following the intervention to assess for diet quality. Parents and students will also be asked to provide feedback on the course and the components of the study to gain information on what was done well and what could be improved. Independent t-tests will be used to compare the results between the intervention group and the control and paired t-tests will be used to compare results within the two intervention groups.

Definitions

Key terms	Definitions
Diet quality	An indicator of variety across key food groups relative to those recommended in dietary guidelines. Dietary intake of vegetables, fruits, whole grains and added sugars will be measured to assess for changes in diet quality
Added sugars	Sugar that is added to food during process, cooking, and/or before eating
Sugar sweetened beverage	Any beverage with added sugar
Dietary patterns	The quantity, proportion, and variety of different foods/beverages in diets and the frequency at which they are consumed
Health outcome	The physical and mental well-being of an individual, including not only the length of life but the quality of life

Assumptions

An initial assumption in this study is that participants will answer dietary recall/interview questions honestly and factually. This assumption will likely be met because the identities of participants will be concealed, and their confidentiality will be preserved. Assuring study participants that their responses will be kept confidential will make it much more likely that they will respond honestly. Another assumption is that parents/families will participate in the nutrition education program with the students outside of school hours. To help ensure this assumption is met, parents/head of households will be asked to fill out weekly/monthly slips documenting if home/activities have been completed. While it is possible the parents may sign the slips without participating, efforts will be made to explain the value and purpose of the nutrition program to encourage the participation of the parents prior to the initiation of the program. Another assumption is that there will be a <20% drop out rate of participants. Aside from promoting the purpose and benefit of this program, a \$50 grocery store gift card will be provided to participants at the end of the school year that complete all the required components of the program and study as well as the opportunity to be entered into a raffle to win a gift basket valued at \$500. This incentive is expected to motivate students and their families to participate in the program.

Limitations

Some limitations of this study are that the nutrition program may not have the same impact at different schools or in other communities. If this program is found to be successful, additional studies will need to be conducted in other communities to determine the overall effectiveness of this program on a broad population. Another limitation is that this study will only be able to be conducted at 12 local Milwaukee Public Schools (MPS) to begin with due to available resources and funding. Other limitations of this study are that participating students may not be present for all education sessions and some students may dropout/transfer during the school year.

Delimitations

Inclusion criteria for this study will consist of fourth grade students attending the same MPS-participating school for the entire school year.

Significance

The results of this study will benefit the field of nutrition in community practice because it will show whether a comprehensive nutrition promotion program such as this could have a positive change in student's dietary intake. Following a more nutritious diet has the protentional to improve the student's academic performance, mental health, reduce the risk for developing chronic disease and overall improve the health outcome of these students (Yang et al., 2014). Not only could the student's health outcome be improved, but the health outcome of their family members and peers as well if they share their knowledge and influence.

Summary

It is known that children on average consume more added sugar and less nutritious foods than recommended by the Dietary Guidelines for Americans (DGA). This poses a serious problem as high sugar intake is correlated high rates of obesity and chronic disease (Yang et al., 2014). It is clear action needs to be taken to improve the diet quality of children and there have been many nutrition education programs implemented at schools world-wide that have had successful results. However, there have not been many school-based nutrition programs that include parental involvement and are led by highly educated nutrition professionals such as dietitians. The effective implementation of this study will allow researchers to evaluate the impact of a nutrition education program such as this. Feedback from both parents and students will also be encouraged to gather valuable information on the difficulty of completing dietary recalls and home activities as well as the value the parents and children place on the nutrition program provided. The data and feedback obtained from this study can help determine if efforts should be made to implement a nutrition program such as this in more schools as core curriculum.

Chapter 2: Review of the Literature

An extensive review of literature regarding interventions to improve dietary intake in children was conducted. Parental and household factors have been found to have a significant impact on children's dietary intake (Dunaway et al., 2017). For this reason, some interventions have been done that focused on targeting parent nutrition-related knowledge and behaviors with the goal of improving their child's diet quality. Meanwhile, other studies have been conducted by authors to evaluate the effectiveness of an intervention directly targeting the child with the goal of improving their own nutrition related behaviors and attitudes. Some authors have decided to target both parent and child in hopes that this approach will result in the greatest outcome.

While a lot of interventions have had promising results in improving the dietary intake and health outcome of children, there are some studies with little to no success. The success or lack thereof can be contributed to controllable factors in some cases, but uncontrollable factors as well. The purpose of this literature review is to evaluate key features of these studies in hopes to develop and implement a study that can have the greatest impact.

Literature Research Strategy

Research articles were primarily found using PRIMO, Mount Mary University's Haggerty Library online catalog. Key phrases such as "intervention to reduce sugar intake in children", "school-based nutrition education", "impact of sugar intake on health" and "intervention to increase vegetable/fruit intake in children" were utilized. Primary, peer reviewed research articles were assessed from PubMed Central, EBSCO Host and Nursing and Allied Health Databases. Abstracts of articles were first assessed to determine relevance to the purpose of this review. If relevant, articles were then thoroughly read and assessed for quality and ability to use in this review.

Interventions to Reduce Child Sugar Consumption

Parent-Delivered Intervention

Use of Smart Phone App. Bradley et al. conducted an intervention called Changes 4Life Sugar Smart, this was a national health marketing campaign in a community setting in England. The study included 539 children ages 5 to 11 years old, and their parents. Participants were of various socioeconomic status, ethnic groups, and from various areas in England. Advertising to support this campaign ran on television, billboards, and digital advertising for 6 months (Bradley et al., 2020). A free app, Sugar Smart, was made available for participating parents to download, allowed users to scan barcodes on food and drink packaging to find out how many grams of total sugars were contained in the product. Packets that contained information and tools to help them cut down on their child's sugar intake were also distributed to the participating parents. Parents were asked to report their child's dietary intake using an online 24-hr dietary recall system at baseline, peak intervention, immediately post intervention, and 12 months following the intervention. Qualitative telephone interviews were also completed with 20 parents to get feedback on their impression of the study. Bradley et al. found that total sugar intake decreased an average of 6.2 g/day at peak campaign. The percentage of energy from free sugars significantly decreased across all assessment points except at 12-months, post campaign. The qualitative telephone interviews found that time constraints, the normalization of sugary treats,

and confusing information were the greatest barriers the parents experienced in reducing their child's sugar intake (Bradley et al., 2020). The results indicated that the Changes 4Life Sugar Smart campaign was successful in decreasing sugar intake however, not necessarily long term.

The Changes 4Life Sugar Smart campaign gathered important feedback from participating parents which may allow for improved effectiveness of public health campaigns developed in the future. Some positive feedback received by the mothers is that they liked the Sugar Smart app because it provided their child with a visual rather than simply a number they would not understand (Bradley et al., 2020). When assessing the results of this study, it is important to realize that the parents included in the study may have been more motivated to make changes in their child's diet temporarily because they were hyperaware their child's sugar intake would be documented. Additionally, the parents included in the study were selected from the Public Health England Change4Life database and may already have been more motivated to make changes to their child's diet (Bradley et al., 2020). Regardless, this intervention was successful in reducing sugar-consumption in children and similar trials of this study could be implemented in various communities to assess the effectiveness of this campaign elsewhere.

Use of Authoritative Food Parenting Practices. Food, Fun, and Families (FFF) is another community-based program that aimed to decrease added sugar intake as well as solid fat intake in children (Fisher et al, 2019). FFF is a 12-week program developed with the purpose of decreasing the intake of calories from sugar and fat in preschool children from low-income families. This program utilized authoritative food parenting techniques that emphasized the use of structure and autonomy support in feeding. This was done by promoting the development of eating routines, setting limits, and providing children with guided choices at mealtimes. Autonomy support practices were also encouraged such as including effective praise and parental modeling. In the education sessions, mothers were educated on "WHOA" foods and beverages as well as the healthier "GO" choices. "WHOA" foods include items such as sugar sweetened beverages, french fries, potato chips and desserts. "GO" foods include items such as water, low-fat milk, fruit, vegetables, and whole grains. Lessons particularly emphasized limiting sugar sweetened beverages. This education was provided in 60-min weekly in-person group sessions. Sessions started with a group discussion regarding progress on weekly goals and problem-solving around challenges the mothers were experiencing in meeting their goals. Dietary recalls were completed at baseline and post-intervention and included recalls from two weekdays and two weekend days. The recalls were collected over the phone by trained staff. Researchers found that the intervention was effective in significantly (p < 0.05) decreasing the number of calories the children consumed from solid fat and added sugar.

The Fischer study is an important resource because it evaluates how parents can be educated to promote positive changes in their child's diet. Parent support is an important factor in creating child behavior change which can ultimately impact health outcome (Fisher et al, 2019). However, it is important to note that this study only measures short term and not longterm adherence to the positive health behavior changes. In order for this program to have the largest impact, it is important to consider what follow up tactics can be used to encourage these mothers to continue the authoritative food parenting practices. To assess the effectiveness of this, it would also be of benefit to assess these individuals' behaviors and their child's dietary intake and anthropometric data a year after the intervention.

Intervention Targeting both Mother and Child. Smart Moms was another parentbased program developed to reduce sugar sweetened beverage and juice consumption by children ages 3-5 years old and reduce maternal weight (Nezami et al., 2018). This was a smartphonedeveloped intervention that occurred over 6 months. Mothers with a body mass index of 25–50 kg/m² and, who had a child between the age of 3 to 5 years old that consumed at least 12 oz of sugar sweetened beverages or juice daily were included in the study. Intervention participants attended one 75-min in-person group session and received phone-based interventions which included lessons on a mobile website and text messages. The primary outcome of child sugar-sweetened beverage/juice intake was assessed using one weekday in-person 24-h dietary recall at baseline, 3 months, and 6 months. According to the results of the study, children in the Smart Moms intervention group consumed significantly less sugar sweetened beverages and juice at 3 and 6 months. Mothers in the intervention group also consumed significantly less sugar sweetened beverages 6 months into the intervention targeted behavior change in both children and mothers. Children often model their behavior based on their parents, so an intervention that targets both could result in a stronger outcome.

Child-Delivered Interventions

Community Food Environment. Large supermarket chains tend to be less prevalent in low-income urban communities and instead these community members are left to rely on smaller corner grocery stores. These stores tend to not have nutritious options such as, fresh fruits and vegetables and instead are filled with processed, packaged goods. One study found the prevalence of obesity tends to be higher in areas that have more of these small grocery stores and fast-food restaurants and lower in areas that had larger supermarkets (Moorland et al., 2008). This indicates that the type of food stores available may substantially influence dietary intake of individuals and impact their health outcome.

The B'more Healthy Communities for Kids (BHCK) was a childhood obesity prevention trial conducted in Baltimore City with the purpose of improving the food environment outside of school (Trude et al., 2018). The intervention sought to increase the availability of more nutritious food options over the high-sugar, high-fat beverages and snacks typically found in small food stores. Nutrition education sessions were provided to 9-15-year-old children at community recreation centers in hopes to increase the demand for these healthier items. BHCK partnered with wholesalers, corner stores and carry out stores within the community and worked to improve the supply of healthier options at these locations. Gift cards were provided to the smaller stores to assist in purchasing healthier items. BHCK worked to improve the demand for these healthier items with the provision of nutrition education classes, point-of-purchasing promotion and giveaways, in-store taste tests, and the use of promotional posters and handouts. Participating individuals completed a Child Impact Questionnaire that contained 79 questions pertaining to food purchasing habits and demographics. A Food Frequency Questionnaire was also completed to collect dietary intake information of the participating youth. Trude et al. found that the BHCK intervention significantly decreased the percentage of calories consumed from sweet snacks and desserts. The participating youth in the BHCK intervention also purchased 1.4 times more healthier foods and beverages per week in comparison to the control group. These findings suggest that interventions to increase the availability of nutritious foods in low-income communities and the promotion of these items may lead to healthier food purchasing and decrease youth's consumption of sugar sweetened items.

Creating a positive environment for healthy eating is not limited to the promotion and availability of healthy foods, but also to limit less healthy options available to children. Highly processed foods that have a large amount of fat, salt, or sugar (HFSS) are often advertised through commercials, social media, celebrity-endorsements, and in-store promotions. High exposure to marketing of HFSS food products can influence children's perception of these foods and ultimately impact their consumption patterns. The government of the United Kingdom realized this issue and began investigating the implementation and effect of new restrictions on marketing for HFSS food. Eleven to nineteen-year-olds in the United Kingdom completed an online survey (Critchlow et al., 2020). Participants were asked questions both on their exposure and awareness to the marketing of HFSS foods and their intake of these foods. For example, participants were asked to complete the statement, "Over the last month, how often, if at all, have you" and were presented with various marketing activities for HFSS foods (Critchlow et al., 2020). For each marketing activity, the frequency of awareness was self-reported using a sixpoint scale. Participants also answered questions regarding their intake of various HFSS foods as well as non-HFSS healthier alternative foods. Researchers found that 90.8 % of participants reported seeing marketing for HFSS foods through at least one activity in the past month and 67% of the participants reported awareness of these marketing activities at least weekly. Significant associations were found between both medium and high awareness of marketing for HFSS foods, and higher weekly consumption of sugar-sweetened beverages, pastries, and crisps. There were also associations between high awareness of marketing for HFSS foods and higher weekly consumption of flavored yogurts and chocolate/sweets. Due to these finding, the authors of this study hypothesize that if the UK government implemented marketing controls of HFSS products, there would be a decrease in consumption of these foods which would benefit public health, specifically adolescent health (Critchlow et al., 2020).

School Lunch Environment. As students consume about 180 lunches at school a year, schools have the potential to positively impact children's health by providing nutritious meals.

A study conducted by Koch (2021) examined the effects of the *Wellness in the Schools* (WITS) programming on school lunch consumption by second and third grade students in New York City public schools. The WITS programming consisted of transitioning the schools from providing the standard menus to an alternative WITS menu that included the addition or expansion of a salad bar, made from scratch entrees, the elimination of chocolate milk as a beverage option, and the addition of a waterjet station if one was not already available. The WITS cooks and cafeteria staff were also trained to encourage students to eat the school lunch and to take and consume the offered vegetables. To assess the effectiveness of this programing, school lunch consumption was measured using the System of Observational Cafeteria Assessment of Foods Eaten (SOCAFE) tool with anonymous observers at both control and intervention school lunch times. These observations were completed in the fall of 2015 and in the spring of 2016 for three consecutive days. The variety and quantity of various food items selected by the students in the cafeteria line was measured as well as the amount of these items consumed during the lunch period. Researchers found that the students from the WITS schools ate significantly more fruits and vegetables than the students in the control schools. By eliminating the offering of chocolatemilk at WITS intervention lunches, the students did not have access to sugar-sweetened beverages provided by the school at lunch so thus, consumed significantly less of these items. However, students from the WITS intervention also consumed 21% less milk overall in comparison to the control group. This is important to consider when weighing the pros and cons of not offering chocolate milk as a beverage option (Koch et al., 2021). Overall, this intervention shows that providing more nutritious options at school lunch can improve the diet quality of students.

A multi-component intervention that focused on altering the school lunch environment to improve student vegetable and fruit intake was conducted at three rural elementary school cafeterias and included participants in kindergarten through 8th grade (Hamdi et al., 2020). The four main intervention components included cafeteria decorations, creative names for menu items, social norming taste tests, and flavor stations which were implemented at separate time periods as well as all at once. Plate waste, phone interviews and observations were used to evaluate the impact of the intervention. Authors of the study found that fruit consumption significantly increased at School 1 during the taste test and flavor station intervention months and at School 2 during the creative names intervention months compared to baseline. Students were three times more likely to select a vegetable during the taste test intervention months at School 3. Cafeteria decorations were not found to have a significant impact on fruit and vegetable consumption but were found to be well accepted from information collected via phone interviews and were found to be easily implemented. While the impact of the interventions was not consistent amongst schools, some positive results were found by authors following the implementation of this study. It would be beneficial for these interventions to be conducted at more schools to see if more consistent results could be found.

Promoting Water at Schools. A controlled trial was conducted to help the authors evaluate the effect of the social marketing developed "Water Campaign" on sugar-sweetened beverage consumption. A select group of primary schools in the Netherlands were included in the intervention group, non-participating schools were the control and continued with their regular health promotion program. The Water Campaign included lessons at the intervention schools and integrated community activities that encouraged water consumption in favor of sugar sweetened beverages. Researchers found that the intervention group consumed significantly more water and less sugar sweetened beverages (Kruitwagen et al., 2014). This study was unique in that it utilized the promotion of a positive health behavior (drinking water) with the purpose of decreasing a negative health behavior (consuming sugar sweetened beverages).

Twenty-two public schools in Rio de Janeiro, Brazil also participated in a healthy lifestyle education program that promoted water consumption to fourth graders in hopes that it would result in a decrease in sugar sweetened beverage intake and prevent excessive weight gain (Sichieri et al., 2009). Over the course of one school year, the healthy lifestyle education program was delivered to the students using simple messages encouraging water intake over sugar sweetened beverage intake. The students participated in classroom activities by creating drawings and songs about the importance of water and how much the body needs it. Anthropometric data and intake of sugar-sweetened beverages/juice was measured at baseline and at the end of the trial. Researchers found that following the program, the intervention group consumed significantly less soda than the control group, however it was also found that the intervention group reported drinking more juice than the control group after the program. There was no statistically significant reduction in BMI overall for the intervention vs control group, but there was a statistically significant reduction in BMI among students, who were overweight at baseline (Sichieri et al., 2009). This indicates that interventions to reduce added sugar intake may result in weight loss for overweight adolescents, but not necessarily for adolescents with a normal or underweight BMI.

The Ministry of Health and Long-Term Care in London, Ontario implemented a program that did not quite result in the desired outcome. The program was called *Water Does Wonders*, it promoted water consumption with the hopes that children would consume more water and less sugar-sweetened beverages (Irwin et al., 2019). Schools participating in this program each received a new automatic water bottle filling station and implemented an education program at their school to promote healthy beverage consumption. Unfortunately, this intervention was not found to be successful as water and SSB consumption did not significantly change from baseline to post-intervention. However, authors of this study felt that the absence of positive results may be due to lack of adherence to the education program, improved devotion to the program could possibly occur by offering the schools an incentive for sticking with the program and following it precisely.

Discouraging Sugar-Sweetened Beverages at Schools. Another school-based intervention with the purpose of reducing sugar-sweetened beverage consumption was conducted in Shanghai, China. While end goals were similar to the previous studies, this intervention focused on educating students about SSB consumption rather than focusing on the promotion of water. A total of 2,202 students were randomly recruited from elementary and middle schools in Shanghai and were randomly assigned to the intervention and control group. The nutrition education intervention was conducted over one year by the teachers in the intervention schools, with the collaboration of public health doctors. The program focused on providing sugar-sweetened beverage (SSB) related material, praising students with outstanding health behaviors, distributing promotional cards to students, and creating a blackboard painting activity with the theme of "understanding SSBs". A sugar-sweetened beverage frequency questionnaire was completed to collect information on SSB intake and frequency over the past 3 months both at baseline and after the one-year intervention. Researchers found that the intervention group consumed significantly less SSB than the control group (Zhu et al., 2021).

Child-Delivered Intervention with Parent Involvement

Discouraging Foods with Added Sugar. A nutrition education program was conducted in Korea with the primary purpose of reducing sugar intake in the pre-school children. A total of one hundred-eighty-eight children were recruited in ten pre-schools located in Seoul, Korea (Ma-Young et al., 2019). The enrolled children were then divided into two groups, the nutrition education group and the control group. The nutrition education program included hands-on and interactive activities such as, cooking lab, play, activity, animation, songs, and visual materials. The contents of the program were created with the purpose of discouraging foods with added sugar, such as baked goods, beverages, sweetened milk, yogurt, and ice cream. In contrast, fresh nutrient dense foods were encouraged to maintain healthy diet habits. All nutrition education materials and contents were provided to the parents of the children to also help promote healthier meal intake at home. After the 11-week nutrition education program, trained interviewers obtained food recalls for each child on two weekdays and one weekend day. Pictures of the food served at the pre-schools were taken by the teachers before and after eating and the actual intake sugar, fiber, macronutrients, and micronutrients were analyzed using CAN Pro 5.0 software. Researchers found that the nutrition intervention group consumed significantly less total sugar than the control group. Ma-Young et al. also found that the consumption of sugar sweetened beverages and yogurt was 14.97% in the educated group and 19.77% in the non-educated group, but this was not a statistically significant difference. However, the education group did consume significantly less sugar sweetened bread, cookies, and rice cakes than the control group. The findings are important as it suggests that a nutrition intervention aiming to decrease the amount of added sugar in children's diets may not only be successful in decreasing sugar intake, but also increasing nutrient density of children's diets as well (Ma-Young et al., 2019).

A strength of this study was that it did not solely rely on the accuracy of human recall. Having pictures taken of meals provided to the children before and after consumption made the assessment of dietary intake a lot more reliable. With the widespread use of smart phones, before and after photos of meals and snacks would be very feasible and could be used in addition to, or in replacement of, dietary recalls to better improve the accuracy of intake assessments. A weakness of this study is that baseline dietary recalls were not completed for the intervention and the control groups. This undoubtedly decreases the validity of the results because it cannot be known if the intervention group may have consumed less sugar sweetened foods at baseline. Another weakness is that while the authors of the study state the parents were provided with the nutrition education materials from the program, it does not say if parents had to sign off on whether they reviewed the materials or if there was any direct interaction with the parents about the information provided aside from simply sending it home with them. While the idea of this hands-on, interactive nutrition education curriculum seemed promising for success, the study conducted to assess the effectiveness of this intervention could be stronger (Ma-Young et al., 2019).

A Salt Reduction Intervention with Considerations for Sugar Reduction

Interventions. While not related to sugar consumption, a school-based nutrition education program with parent involvement was conducted in China with the purpose of reducing salt consumption (He et al., 2015). Children in their 5th year of primary school were included in this study. Participating schools were randomly assigned as the control group or intervention group. Over the course of one 3.5-month school term, children from schools in the intervention group were educated on the harmful effects of salt and how to reduce salt intake throughout their school's usual health education lessons. Children then were asked to deliver the salt reduction

message to their families. As homework, children were asked to share the 50% salt reduction target with their family and deliver the salt reduction methods and tips they were taught at school. Parents were also provided with educational materials and a family quiz to complete on the information provided. The primary outcome of difference in salt intake between the intervention and control group was measured by 24-hour urinary sodium from baseline and at the end of the intervention. The secondary outcome of difference in salt intake between the intervention and control group was the difference between the two groups in the change of blood pressure. He et al. found that both the children and adults in the intervention group had significantly lower levels of urinary sodium compared the control group. Researchers also found that parents in the intervention group had significantly lower blood pressure, but there was no statistically significant difference in blood pressure amongst the children (He et al., 2015).

The use of randomization and large sample size are some strengths of the study. Another strength is the inclusion of a family completed quiz, so it is known if the participating parents are reviewing the education information provided and discussing with their child. Also, by using the 24-hour urinary sodium test and blood pressure as measurements, you eliminate some inaccuracy of human recall. However, it also would have been beneficial to include a 24-hour dietary recall as other biological and physiological factors may impact both the urinary sodium level and blood pressure measurements. This intervention was particularly impactful because by including the students' families, it not only allowed the health promotion education to reach more people, but the students were also likely greater effected by having their families involved. Overall, this was a strong study and certain aspects of this program could be utilized when developing a nutrition education program with the purpose of reducing sugar consumption in students and participating families.

School Garden Program. A school-based randomized- controlled trial was conducted to assess the impact of a one-year school-based gardening, nutrition, and cooking intervention in elementary school children at in Texas (Davis et al., 2021) Sixteen elementary schools within a 60-mile radius of Austin, Texas was included in the study. Eight schools were randomly selected to receive the Texas Sprouts Intervention and 8 schools were selected to serve as the control and received a delayed intervention. The Texas Sprouts intervention consisted of a 0.25-acre outdoor teaching garden and 18 lessons that were each 60-minutes in length. The lesson contained topics on gardening, nutrition, and cooking and were taught by trained educators. Every lesson included either a garden taste test or a cooking activity. Parents of the participating students were also asked to participate in the Texas Sprouts intervention and were provided nine 60-minute education sessions throughout the school year. The education sessions included topics such as the importance of family eating, healthy shopping, and increasing home available and access of healthy foods. Parents were incentivized to attend the lessons with the provision of free childcare for their children, produce giveaways, raffles for gift cards, and more. Anthropometrics, blood pressure, and dietary intake data on both the children and parents was collected at baseline and post intervention.

On average, 96% of students attended each of the 18 lessons provided (Davis et al., 2021). In contrast, only 7% of parents attended 1 of 8 provided lessons and < 1% of parents attended 50% of the provided lessons despite incentivization and offers to reschedule classes. The data collected by the authors showed that following the intervention there was a significant increase and vegetable intake, however the intervention did not have any significant effect on BMI, blood pressure, or added sugar intake. While this study did have the potential to assess the impact of a school-based program with parent involvement, it was unsuccessful in doing so due

to such low parent participation. Some thought should be put into tactics to improve parent participation rates such as offering virtual lessons as an alternative, increasing the value of incentives offered, and decreasing the length of the lessons. While this program was not found to be effective in reducing obesity markers and blood pressure, it is possible that it could over a longer period.

Promoting Fresh Fruits/Vegetables vs. Discouraging High-Fat/High Sugar Intakes.

Epstein et al. conducted a study that included families with at least one obese parent and one non-obese child aged 6 to 11 years old. These families were recruited by physician referrals, posters, newspapers, and television advertisements for the *Childhood Weight Control and Prevention Programs* at the University of New York. Participating families that met the specified criteria were randomly split into two groups, one with an intervention aimed to increase fruit and vegetable intake and one that focused on a decreased high-fat/high-sugar food intake. Both groups received education on topics such as weight control and prevention, the *Traffic-Light Diet*, and developing a healthy eating environment for children throughout 14 education sessions. The difference between the interventions is that the emphasized goal of the Increase Fruit and Vegetable group was to incrementally increase the intake of fruits and vegetables to reach at least two servings of fruits and three servings of vegetables per day while participants in the Decrease Fat and Sugar group set incremental goals to decrease their consumed servings of highfat/high-sugar foods to no more than 10 servings per week. Anthropometric measures and food intake measures were collected for both parents and children at baseline and 12 months.

As may be expected, authors of the study found that the Increase Fruit and Vegetable group had a higher increase in fruit and vegetable intake between groups and the Decrease Fat and Sugar group had the greatest decrease in consumption of high-fat/high-sugar foods (Epstein et al., 2001). However, the Decrease Fat and Sugar group did not have a statistically significant increase in vegetable/fruit consumption following the intervention, but the Increase Fruit and Vegetable group did have a statistically significant reduction in high-fat/high-sugar intake following the intervention. Additionally, the percentage of weight loss was greater for parents in the Increase Fruit and Vegetable group than the Decrease Fat and Sugar group. These results may indicate that focusing on what is encouraged to be eaten versus focusing on what should not be consumed may make it easier to adhere to the caloric reductions needed for weight control.

The Pro Child Intervention uses a similar concept by focusing on increasing vegetable and fruit intake in children. The Pro Children Intervention was a multi component intervention consisting of a classroom component, a school component, and a family component in Spain, Norway and the Netherlands among mothers of 11-year-olds (Te Velde et al., 2008). The Pro Children Intervention program included both classroom and home-based activities that focused on vegetable and fruit intake such as, taste-tests, learning how to prepare produce, a recipe competition, creating a poster and more. Fruit and vegetable intake was assessed with the use of questionnaires completed before the intervention, immediately after the first year of the intervention, and 1 year later. Te Velde et al. found that the intervention group consumed significantly more fruit and vegetables immediately after the first year of intervention with a 20 % higher fruit and vegetable intake in comparison to children from the control group schools. However, statistically significant differences in the consumption of fruit and vegetables between the intervention and control group was not found one year following the intervention (Te Velde et al., 2008). Since the previous studies found that a nutrition education intervention focused on increasing fruit and vegetable consumption also resulted in a decrease in sugar intake, it would have been interesting if this study also assessed the amount of sugar consumed.

Home-Based Intervention

Promotora-Led. According to National Center for Health Statistics (NCHS) data from 2015, approximately 16.7% of Latino preschool children are obese, which is a higher rate of obesity than other racial/ethnic groups (Ogden et al., 2015). This shows a need for culturally appropriate, obesity interventions effective for Latino children. *ANDALE Pittsburgh* is a program that was developed that included Latino parents and their two to five-year-old children. *ANDALE Pittsburgh* stands for Actividad, Nutrición, y Diversión, Apoyando a los Latinos En Pittsburgh (Physical activity, nutrition, and Fun, Supporting Latinos in Pittsburgh). In this intervention, Promotoras, community members who are trained to provide health education and share characteristics with the priority population, led a 10-week home-based intervention. The focus of the intervention was to promote a healthy weight in Latino pre-school children by improving dietary intake, decreasing sedentary behavior, and increasing physical activity (Taverno Ross et al., 2018).

A total of ten, 90-minute weekly sessions were provided that included an education, practice, and activation component. Promotoras provided the session content related to the weekly topic, the families would then participate by completing hands-on-activities and role play, and then the families would set goals and problem solve together. Data was collected on child physical activity by use of an accelerometer that was worn for 7-10 days prior to the intervention, child and parent dietary intake was collected by use the validated Block Food Screener, anthropometric data of both parent and child collected, and parents completed a survey that included questions on topics such as parent/child screen time, parent health behaviors, parent self-efficacy and parental support. The same information was also collected following the intervention. Authors found that while there was not a significant decrease in BMI amongst all preschoolers at baseline and follow-up, there was a significant decrease in BMI percentile for overweight and obese children from baseline to follow up. Significant differences were also seen in dietary intake such as an increase in fruit, vegetable, and water intake. The authors also found that there was a significant decrease in saturated fat, added sugar and sugar-sweetened-beverage intake. There was not a significant increase in physical activity among the preschoolers but there was a significant increase in physical activity amongst the parents. All in all, this program showed promising results on its ability to promote a healthy weight in Latino preschool children. A longer-term follow up would be needed to determine the true effects this program has on BMI. This study provides good insight that a home-based intervention that promotes well-rounded healthy lifestyle practices can be effective in reducing sugar intake by Latino preschoolers (Taverno Ross et al., 2018).

Research Methodology

This literature review has provided great insight on the effectiveness of various approaches to reduce sugar intake and improve diet quality in children as well as insight on the strengths and weaknesses of key study design characteristics. When possible, it is best to conduct a randomized controlled trial to reduce bias and minimize the risk of confounding factors impacting the results of the study (Hariton et al., 2018). Selecting the right sample size is also a very important part in improving the power of the study, the sample size should be large enough to effectively represent the population without being too large that it may be difficult to conduct properly and waste resources (Guerrera et al., 2017). Methods to increase participation rates are also very important, completing the intervention should be viewed as worthwhile for best participation. It is also of value to assess how participants viewed the program following completion of it and to be accepting of any feedback on it to take in consideration for future

improvements. Multiple studies reviewed did not find significant effects of the intervention on various anthropometric measures and authors discussed this may be because the study was not evaluated over a long enough period of time, this should be considered in selecting the duration of the study.

Summary

Many children consume far more than the recommended amounts of added sugars and solid fat in their diet and include far less than the recommended amounts of fresh fruits and vegetables in their diet (USDA, 2020). It has also been shown that poor diet quality can have a significant, negative impact on health outcome (Yang et al., 2014). It is clear that something needs to be done to improve the diet behaviors of young children and adolescents, but the question is: what are the best interventions to solve this public health crisis? Many studies have been conducted to help assess the effectiveness of parent-based interventions in reducing the sugar-intake of their children (Fisher et al, 2019; Bradley et al., 2020) and there are studies on school-based interventions provided directly to children (Koch et al., 2021; Kruitwagen et al., 2014) but there is not a lot of research on school-based interventions with parent involvement. Children are very curious beings who may be less likely to follow their parents' encouragement to decrease sugar intake without understanding the purpose of doing so. In contrast, if children are taught the importance of reducing sugar-intake at school but then come home to pantries filled with sugar-sweetened products and see their familial role models consuming these products, they will presumably be less likely to decrease their sugar intake despite their knowledge regarding the importance of this.

The impact of environment on dietary intake should also not be disregarded. If children are taught about the importance of consuming a healthy diet but do not have access to healthy

meals at their school or around the community they dwell in, that is a significant barrier in translating nutrition knowledge to positive diet behaviors. It is also important to note that the interventions that included interactive activities for the children had better results. For this reason, it is believed that a multicomponent program that includes school-based nutrition education, interactive activities, the provision of healthy school lunch and active parent involvement would have the largest impact on diet related behavior change and reducing the intake of added sugars by children. It would take a significant amount of work and resources to develop and implement a program such as this, but if conducted correctly the program could decrease child sugar consumption and ultimately improve children's diet quality which would be well worth the time and resources spent.

Chapter 3: Methodology

This chapter outlines how the multicomponent, school-delivered nutrition education program with parent involvement will be implemented and evaluated. Many steps will need to be taken to ensure the program runs smoothly and necessary information is gathered. Topics discussed in this section include research protocol, study design, data collection process, instrumentation, data analysis plan, threats to validity and ethical procedures.

Research Protocol

The research question that will be tested is: Will the nutrition education program have a significant impact on participant dietary intake? I hypothesize that children enrolled in the nutrition education program will consume less added sugar and consume a higher quantity of fruits and vegetables in comparison to the control group.

Table 1

Hypothesis	Independent variable	Dependent variable	Confounding variables
Intervention participants will consume less added sugar	Nutrition Education Program	Average daily intake of added sugar	Nutrition education provided at physical education class or at extracurriculars, Resources provided in the community, family size, family income level, parent employment status, gender, ethnicity, weight, primary- language
Intervention participants will consume a higher quantity of vegetables	Nutrition Education Program	Average daily intake of vegetables	Nutrition education provided at physical education class or at extracurriculars, Resources provided in the community, family size, family income level, parent employment status, gender, ethnicity, weight, primary- language
Intervention participants will consume a higher quantity of fruit	Nutrition Education Program	Average daily intake of fruit	Nutrition education provided at physical education class or at extracurriculars, Resources provided in the community, family size, family income level, parent employment status, gender, ethnicity, weight, primary- language

Hypothesis and confounding variables

Study Design

The study will be a randomized controlled trial. This study design was selected because it is considered the "gold standard" when evaluating the effectiveness of a program (Guerrera et al., 2017). Within twelve participating MPS schools, fourth grade classrooms will be randomly selected as control or intervention groups. Intervention/Control groups will complete dietary recalls on the same specified days. The control group allows for confounding variables to be controlled for which can increase the validity of the study. While it would not be possible to blind participants and educators on whether each group is the control or intervention group, trained dietary interviewers will be blinded from whether participants are in the control/intervention group when collecting dietary recalls to reduce the risk of bias.

Setting and Sample

The study will take place in Milwaukee, Wisconsin at various Milwaukee Public Schools (MPS). MPS is the largest school district in the state of Wisconsin with approximately 5,700 fourth grade students enrolled in 2018 (MPS, n.d). MPS has a high population of minorities and students from low-income families. Students from MPS have a history of scoring significantly lower in standardized testing in comparison to other public schools in Wisconsin (Public School Review, n.d). This data is of importance due to research that indicates minorities, low-income individuals and people with low educational attainment are at higher risk for having poor diet quality (McCullough et al., 2022). Inclusion criteria for this study will consist of fourth grade students attending the same MPS participating school for the entire school year. Students that do not complete all dietary recalls and compete/attend <80% of the nutrition education classes and activities will be excluded from the study.

The goal of the study will be to include at least twelve MPS schools with a minimum of 40 fourth grade students. Schools will be screened on the likeliness to have the minimum number of participants enrolled by looking at past enrollment information on the District Enrollment and Demographics Page on MPS website. Superintendents of MPS schools that may meet the minimum enrollment will be contacted regarding their willingness to participate in the education program. By including ten MPS schools with a minimum of 40 fourth grade students each, the potential sample size is >/= 480 participants. However, there is the possibility that a significant portion of the students/parents will elect to not participate in the study. In order to meet the suggested sample size, at least 75% of these student/parents must agree to participate in the study. The suggested sample size for this study is 360 participants. This sample size was determined using the Qualtrics sample size calculator set to a 95% confidence interval with a 5% margin of error (Qualtrics, 2022). The total population size of 5699 fourth grade students enrolled at MPS in the year 2018-2019 was used to produce an ideal sample size of 360 students.

Data Collection Process

A registered dietitian will deliver a nutrition education curriculum that contains topics such as the importance of a nutritious diet, building a balanced plate, the function of macronutrients and micronutrients in our body, the importance of hydration and more. This curriculum will be based off the Nutritious, Delicious, Wisconsin and Serving up MyPlate curriculum (Williams et al., 2022) (USDA, n.d). Nutrition education will be delivered by the registered dietitian over 18 nutrition education classes to the intervention students. The lessons will be 60-minutes long and will be conducted over the course of one school year, which is approximately 41 weeks long. Students will be sent home with a printed summary of the lesson taught that week and will be asked to review it with their parents and return a signed slip the following week indicating that this was completed. Please see Appendix B for the Nutrition Class Summary Slip.

Students and parents will also be encouraged to complete at least one suggested activity each month. Suggested activities can be found in the binder that will be provided to all intervention participants at the beginning of the year. Contents of the binder will include healthy, age-appropriate recipes, fun educational games related to nutrition and suggested activities. Some activity suggestions may include "Try a vegetable you have not had before," "Practice your fruit and vegetable knowledge using the Fruit and Vegetable Flash Cards," (USDA, n.d) or "Try a new recipe from MyPlate" (USDA, n.d). More suggested monthly nutrition activities can be seen in Appendix C and the slip that parents/guardians must sign to indicate the completion of a monthly activity can be seen in Appendix I.

Instrumentation

A tool called Research Randomizer will be used to randomize the fourth-grade classrooms at each participating school to determine which will be the intervention group and which will be the control group (Generate Numbers). All participating students will be asked to complete 24-hour diet recalls both prior to the intervention and following the completion of the intervention with the help of their parents. The 24-hour diet recalls will be conducted over two school days and two weekdays. The parents of the students will report their child's dietary intake to trained staff at the Nutrition Coordinating Center (NCC) over the phone and the Nutrition Data System for Research (NDSR) dietary analysis software application will be utilized. The NCC is located in the University of Minnesota's School of Public Health and was initiated in 1974 with the mission to support nutrition research by providing state-of-the-art software and databases for assessing food and nutrient intake. NDSR utilizes a multiple pass approach when collecting dietary recalls, reducing the risk of inaccurate reporting (University of Minnesota, n.d). Additionally, before/after consumption pictures will be taken of the student's lunch by staff to help provide accurate intake information when the parents are not around to help document.

Funding

The *Pioneering Ideas: Exploring the Future to Build a Culture of Health* grant from the Robert Wood Johnson Foundation will be used to fund this program and study (RWJF, 2022). The money that will be received from this grant will be used to pay the Dietitian's salary, purchase gifts for the participants and materials used in the program, pay for the Nutrition Coordinating Center, and will be used for other costs that may occur when conducting this program.

Data Analysis Plan

Independent group t-tests will be used to compare the average results between the intervention group and the control group. For example, the independent t-test will be used to compare the average race/ethnicity and gender distribution of the control and interventions groups. Paired t-tests will be used to compare results within the intervention groups. For example, the paired test will be used to compare the average consumption of added sugar amongst the intervention group prior to the nutrition education program in comparison to the average consumption of added sugar in the intervention group upon the completion of the nutrition education program. Excel software will be used to determine the results of all statistical tests mentioned by using the t-test function to find the p-values.
Table 2

Descriptive Statistics

Research Question	Independent	Level of Measurement	Dependent	Potential Responses	Test of Significance
la.	Nutrition Education Program	Ratio	Average daily intake of added sugar intake	Grams of sugar (0- unlimited)	Independent t-test and paired t-test
1b.	Nutrition Education Program	Ratio	Average daily intake of vegetables consumed	Cups of vegetables (0- unlimited)	Independent t-test and paired t-test
1c.	Nutrition Education Program	Ratio	Average daily intake of fruit consumed	Cups of fruit (0- unlimited)	Independent t-test and paired t-test

Threats to Validity

While there are some controlled aspects of this study, there will be many factors that are uncontrollable and will be threats to the validity of this study. There is potential for historical threats to validity, which are unrelated events that may influence the outcome. An example of a potential historical threat would be a participating student throwing a birthday party on a day when one of the 24-hr diet recalls is collected and inviting their classmates to the party and many members of the class consume more sweets and fried food than they otherwise typically would. Interaction between intervention and control students can also be a threat to validity due to a potential influence one another's behaviors. For example, a student from the intervention group shares what she has learned with a student in the control group who then shares this with her classmates and behaviors are influenced as a result. Lastly, with any study conducted over time there is the potential threat of maturation. It is possible that the participants knowledge of nutrition would have grown over time regardless of the program and thus their dietary intakes would improve as well. Utilizing a control group for comparison should help when assessing the outcomes of the study and control for any changes that would have occurred as a natural result of time ("Stating the obvious", 2013).

Ethical Procedures

It will be of utmost importance that this study will be conducted ethically. IRB approval of the study will be obtained prior to the recruitment of participants, please see Appendix J for further details. There will be informed consent of all participating students and their parents, please refer to Appendix K for this document. Students will be asked to complete an assent form to show that they agree to participate in the study, please see Appendix L. A thorough explanation of the program and study will be provided, and participants may drop out at any time. It will be required for parental consent and assent forms to be signed prior to the initiation of the study. Participation in the study will be voluntary, however it will be up to the discretion of the parents to determine if students are allowed to opt out of the nutrition coursework. There will also be practices of responsible conduct of research. Data collectors will be blinded when possible, such as in the collection of 24-hr diet recalls, any potential conflict of interests will be identified and shared in the study publication and all findings will be reported as accurately and objectively as possible. All information obtained will be kept confidential by the researchers and the researchers will be the only people with access to the data. Information obtained will be stored electronically and will be password protected, all data will be destroyed 3 years after the end of data collection. Individual participants will not be identified in any report or publication about this study.

Summary

The effective implementation of this study will allow researchers to evaluate the impact of this nutrition education program. Feedback from both parents and students will also be encouraged to gather valuable information on the difficulty of completing the at-home activities and the value the parents and children place on the nutrition program provided. By obtaining the data from the results of this study and evaluating the feedback provided, it can be determined if efforts should be made the implement a nutrition program such as this in more schools as core curriculum.

Chapter 4: Anticipated Results

Characterization of Study Participants

A total of 620 fourth grade students from twelve Milwaukee Public Schools (MPS) will be recruited to participate in the study. Student enrollment characteristics from each school can be seen in Tables 3-5. This enrollment data is taken from the 2021-2022 school year details and enrollment characteristics of each MPS district published by the National Center for Education Statistics (NCES). Twelve schools will be randomly sorted into six intervention and six control groups using the Research Randomizer tool (Generate Numbers). This randomization can be seen in Table 6. There were no statistically significant differences found between the intervention and control groups when assessing for gender and ethnicity/race distributions of the sample population used as a model for this study (Table 7-8). Figure 1 shows the predicted quantity of participants that will complete the study.

Enrollment Characteristics

Table 3

Enrollment by grade

Milwaukee Public Schools	Fourth grade students (n=620)
Story Elementary	43
Neeskara Elementary	46
Allen-Field Elementary	73
Lincoln Avenue Elementary	53
Townsend Public School	40
Bethune Academy	63
Burbank Elementary	69
Brown Street Academy	44
Hawley Environmental	45
Barton Elementary	43
Burdick Elementary	61
Cass Street Elementary	40

Note: Enrollment data is based off 2021-2022 school year details and enrollment characteristics shared by NCES

Table 4

Enrollment by race/ethnicity

Milwaukee Public					
Schools	Black	White	Hispanic	Asian	Other
Story Elementary	69.50%	2.30%	4.60%	20.50%	3.10%
Neeskara Elementary	79.80%	2.90%	8.20%	3.80%	5.30%
Allen-Field Elementary	7.10%	2.90%	87.60%	0.00%	1.70%
Lincoln Avenue	15.60%	1.80%	77.20%	0.90%	4.50%
Townsend Elementary	92.50%	0.00%	3.40%	0.00%	4.00%
Bethune Academy	60.00%	0.30%	2.30%	35.70%	1.60%
Burbank Elementary	0.40%	6.20%	78.20%	8.70%	6.50%
Brown Street Academy	94.40%	0.40%	1.60%	0.40%	3.20%
Hawley Environmental	63.20%	4.30%	13.80%	7.60%	11.20%
Barton Elementary	82.00%	2.40%	4.00%	6.00%	5.60%
Burdick Elementary	7.70%	45.10%	36.10%	5.10%	6.00%
Cass Street Elementary	84.80%	3.20%	6.40%	0.30%	5.40%
Average	52.02%	6.24%	28.82%	8.06%	4.79%

Note: Enrollment data is based off 2021-2022 school year details and enrollment characteristics shared by NCES

Table 5

Enrollment by gender

Milwaukee Public Schools	Male	Female
Story Elementary	51.30%	48.70%
Neeskara Elementary	53.10%	46.90%
Allen-Field Elementary	50.10%	46.90%
Lincoln Avenue Elementary	50.80%	49.20%
Townsend Public School	53.70%	46.30%
Bethune Academy	54.90%	45.10%
Burbank Elementary	49.50%	50.50%
Brown Street Academy	52.00%	48.00%
Hawley Environmental	53.00%	47.00%
Barton Elementary	54.40%	45.60%
Burdick Elementary	49.60%	50.40%
Cass Street Elementary	52.20%	47.80%
Average	52.04%	47.62%

Note: Enrollment data is based off 2021-2022 school year details and enrollment characteristics shared by the National Center for Education Statistics (NCES)

Table 6

Randomization of participating schools

Intervention Schools	Control Schools
Total (n=311)	Total (n=309)
Allen-Field Elementary	Story Elementary
Lincoln Avenue Elementary	Neeskara Elementary
Townsend Public School	Bethune Academy
Brown Street Academy	Burbank Elementary
Burdick Elementary	Hawley Environmental School
Cass Street Elementary	Barton Elementary

Table 7

Average gender distribution

	Male	Female
Intervention Group	51.40%	48.10%
Control Group	52.70%	47.30%
p-Value	0.178	0.451

Table 8

Average race/ethnicity distribution

	Black	White	Hispanic	Asian	Other
Intervention Group	50.35%	8.90%	35.38%	1.12%	4.13%
Control Group	59.15%	3.07%	18.52%	13.72%	5.55%
p-value	0.751	0.446	0.502	0.065	0.242

Figure 1

Flowchart illustration of study participants



Dietary Intake Assessment

All participating students in the intervention and control groups will complete dietary recalls at the beginning and at the end of the school year. The predicted average results of the intervention group can be seen in Table 9 and the result of the control group can be seen in Table 10.

Table 9

Intervention schools	' average dai	ly dietary	intake	per 24-hr	diet recalls
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	Sugar (teaspoons)		Vegetabl	Vegetables (cups)		Fruit (cups)	
	Pre	Post	Pre	Post	Pre	Post	
Allen-Field Elementary	16.50	13.00	0.50	1.00	1.50	1.75	
Lincoln Avenue	22.00	17.50	1.00	1.25	2.00	2.00	
Townsend Public School	14.00	12.50	1.00	1.00	1.00	1.25	
Brown Street Academy	17.50	10.00	1.25	1.75	1.25	1.50	
Burdick Elementary	19.50	12.50	0.50	1.00	2.25	2.00	
Cass Street Elementary	16.00	13.00	0.75	1.50	1.75	1.75	
Average	17.58	13.08	0.83	1.25	1.65	1.71	
SD	3.2	29	0.3	35	0.1	37	
p-value	*0.	05	*0.	01	0.3	36	

* $p \le 0.05$ indicates statistical significance. SD= Standard Deviation

	Sugar (teaspoons)		Vegetabl	es (cups)	Fruit (cups)	
	Pre	Post	Pre	Post	Pre	Post
Story						
Elementary	14.00	16.00	1.00	0.75	2.00	1.75
Neeskara Elementary	15.50	16.00	0.75	1.00	1.50	1.50
Bethune Academy	18.00	15.50	0.75	0.75	1.00	1.25
Burbank Elementary	19.50	17.50	1.00	1.25	1.75	1.50
Hawley Environmental	20.00	19.00	0.50	0.75	1.75	2.00
Barton Elementary	22.00	18.50	0.75	0.50	1.75	1.75
Average	18.17	17.08	0.79	0.83	1.55	1.63
SD	2.2	21	0.2	21	0.1	28
p-value	0.2	25	0.0	59]	l

Control schools' average daily dietary intake per 24-hr diet recalls

Summary

Anticipated results were shown in tables 3-10. Chapter 5 will discuss the anticipated findings of the study and how they align with existing research. The strengths and weaknesses of the proposed study will also be discussed, as well as suggestions for future research.

Chapter 5: Discussion

This chapter will discuss the sample population and anticipated results of the proposed study and compare those results from previous studies. The proposed study's strengths and limitations will also be discussed as well as suggestions for future studies

Sample Population

The schools that will serve as the intervention and control sites will be randomly selected. The intervention schools will include Allen-Field Elementary, Lincoln Avenue Elementary, Townsend Public School, Brown Street Academy, Burdick Elementary and Cass Street Elementary with a predicted total fourth grade population of 311 students. The control schools will include Story Elementary, Neeskara Elementary, Bethune Academy, Burbank Elementary, Hawley Environmental School, and Barton Elementary with a predicted total fourth grade population of 309 students. The student sample enrollment characteristics will be based off 2021-2022 school year details and enrollment characteristics shared by the National Center for Education Statistics (NCES). The intervention group student population is predicted to be 51.4% male and 48.1% female, the control group student population is predicted to be 52.7% male and 47.3% female. The differences in these distributions are predicted to be insignificant ($p \le 0.05=$ statistically significant). The difference between the ethnicity/race distribution between the intervention and control groups is also not expected to be significant. The intervention group ethnicity/race distribution is predicted to be as follows: 50.35% black, 8.9% white, 35.38% Hispanic, 1.12% Asian, 4.13% other. The control group ethnicity/race distribution is predicted to be as follows: 59.15% black, 3.97% white, 18.52% Hispanic, 13.72% Asian, 5.55% other.

Interpretation of Results

Dietary intake of fruit, vegetables, and added sugar will be measured prior to and following the intervention for both groups. The average added sugar intake amongst students at the beginning of the nutrition education program is predicted to be 17.58 teaspoons for the intervention group and 18.17 teaspoons for the control group. The average added sugar intake by intervention participants following the nutrition education program is predicted to be 13.08 teaspoons, this is a 25.6% decrease in added sugar intake which is statistically significant (p = 0.05). Added sugar intake is predicted to decrease by 5.9% to 17.08 teaspoons in the control group following the intervention, this difference is not statistically significant (p=0.25). In the intervention group, vegetable consumption is predicted to increase at the end of the

schoolyear compared to baseline but only by .04 cups which is not significant (p=0.69). Fruit intake is predicted to increase in both the intervention and control group, however neither predicted increase was found to be statistically significant. While there was not a statistically significant increase in fruit intake following the intervention, the null hypothesis that the nutrition education program does not have an impact on dietary intake was rejected due to the significant increase in vegetable consumption and decrease in sugar intake measured.

Comparison to Other Studies

There are similarities when comparing to previous studies. For example, Ma-Young et al., 2019 found that a nutrition program in North Korea resulted in students consuming significantly less sugar sweetened bread, cookies, and rice cakes following the program in comparison to the control. Epstein et al., 2001 found that a childhood weight control and prevention program with an intervention aimed to increase fruit and vegetable intake resulted not only in an increase in fruit and vegetable intake, but in a decrease of sugar intake as well. Nezami et al., 2018 also found success with a nutrition program in reducing added sugar intake in 3–5-year-old children. While these studies had nutrition interventions that resulted in positive improvements in dietary intake, not all interventions were as successful in impacting dietary intake (Irwin et al., 2019).

Strengths, Limitations and Suggestions for Further Studies

A strength of this study is the large sample size and inclusion of 12 elementary schools. Another strength of the study is the use of randomization, and that data-collectors will be blinded. A limitation of the study is that 24-hr dietary recalls will only collected on 4 different days and it is possible that there will be some false-reporting. Another limitation of the study is the amount of data that will be collected. In the future, if resources allow, it will be beneficial to gather more anthropometric data such as BMI and blood pressure and biochemical data such as A1c levels. It will also be beneficial to conduct a 5-year follow up with students to assess whether intervention group students still consume more fruits/vegetables and less added sugar than the control students to see if the intervention has long-lasting effects.

Conclusion

With the link that dietary intake in childhood may be related to dietary intake in adulthood (Mikkilä et al., 2005), and the fact that most children consume far more than the recommended amount of added sugar and less than the recommended amount of fruits and vegetables (USDA, 2020), it is important for action to be taken to improve dietary intake in children. One way to do this is to implement nutrition-education programs for elementary school students. Encouraging the involvement of parents in their child's nutrition education curriculum has the potential to elicit stronger positive results. While there are many nutrition education programs that target children, there are few studies that assess the effect of a school-based nutrition education program with parent involvement. The proposed study will allow for more data to be obtained on the feasibility and impact of a program such as this.

References

- AHA. (2022, July 22). Added sugars. www.heart.org. Retrieved September 1, 2022, from https://www.heart.org/en/healthy-living/healthy-eating/eat-smart/sugar/addedsugars#:~:text=What%20is%20the%20Added%20Sugar,day%2C%20or%20about%209 %20teaspoons.
- Bradley, Gardner, G., Rowland, M. K., Fay, M., Mann, K., Holmes, R., Foster, E., Exley, C.,
 Don Bosco, A., Hugueniot, O., & Moynihan, P. (2020). Impact of a health marketing
 campaign on sugars intake by children aged 5-11 years and parental views on reducing
 children's consumption. *BMC Public Health*, 20(1), 331–331.
 https://doi.org/10.1186/s12889-020-8422-5
- Critchlow, Bauld, L., Thomas, C., Hooper, L., & Vohra, J. (2020). Awareness of marketing for high fat, salt or sugar foods, and the association with higher weekly consumption among adolescents: a rejoinder to the UK government's consultations on marketing regulation. *Public Health Nutrition, 23*(14), 2637–2646. https://doi.org/10.1017/S1368980020000075
- Davis, Pérez, A., Asigbee, F. M., Landry, M. J., Vandyousefi, S., Ghaddar, R., Hoover, A.,
 Jeans, M., Nikah, K., Fischer, B., Pont, S. J., Richards, D., Hoelscher, D. M., & Van Den
 Berg, A. E. (2021). School-based gardening, cooking and nutrition intervention increased
 vegetable intake but did not reduce BMI: Texas sprouts a cluster randomized controlled
 trial. *The International Journal of Behavioral Nutrition and Physical Activity*, *18*(1), 18–
 18. https://doi.org/10.1186/s12966-021-01087-x
- Drewnowski, A., & Rehm, C. D. (2014). Consumption of added sugars among US children and adults by food purchase location and food source. The American journal of clinical nutrition, 100(3), 901–907. https://doi.org/10.3945/ajcn.114.089458

Dunaway, Carton Futrell, T., Ma, P., Mundorf, A. R., Keel, K., & Theall, K. P. (2017). Beyond Food Access: The Impact of Parent-, Home-, and Neighborhood-Level Factors on Children's Diets. *International Journal of Environmental Research and Public Health*, 14(6), 662–. https://doi.org/10.3390/ijerph14060662

Epstein, Gordy, C. C., Raynor, H. A., Beddome, M., Kilanowski, C. K., & Paluch, R. (2001). Increasing Fruit and Vegetable Intake and Decreasing Fat and Sugar Intake in Families at Risk for Childhood Obesity. *Obesity Research*, 9(3), 171–178. https://doi.org/10.1038/oby.2001.18

- FDA. (2022, February 25). *Read the Label Youth Outreach Materials*. FDA. Retrieved December 8, 2022.
- Fisher, J. O., Serrano, E. L., Foster, G. D., Hart, C. N., Davey, A., Bruton, Y. P., Kilby, L., Harnack, L., Ruth, K. J., Kachurak, A., Lawman, H. G., Martin, A., & Polonsky, H. M. (2019). Title: efficacy of a food parenting intervention for mothers with low income to reduce preschooler's solid fat and added sugar intakes: a randomized controlled trial. *The International Journal of Behavioral Nutrition and Physical Activity*, *16*(1), 6–6. https://doi.org/10.1186/s12966-018-0764-3
- Generate Numbers . Pair of dice. (n.d.). Retrieved September 17, 2022, from https://www.randomizer.org/

Guerrera, F., Renaud, S., Tabbò, F., & Filosso, P. L. (2017). How to design a randomized clinical trial: tips and tricks for conduct a successful study in thoracic disease domain. *Journal of thoracic disease*, 9(8), 2692–2696. https://doi.org/10.21037/jtd.2017.06.147 Hamdi, Ellison, B., McCaffrey, J., Metcalfe, J. J., Hoffman, A., Haywood, P., & Prescott, M. P. (2020). Implementation of a Multi-Component School Lunch Environmental Change Intervention to Improve Child Fruit and Vegetable Intake: A Mixed-Methods Study. *International Journal of Environmental Research and Public Health*, *17*(11), 3971–. <u>https://doi.org/10.3390/ijerph17113971</u>

Hariton, E., & Locascio, J. J. (2018). Randomised controlled trials - the gold standard for effectiveness research: Study design: randomised controlled trials. *BJOG : an international journal of obstetrics and gynaecology*, *125*(13), 1716. https://doi.org/10.1111/1471-0528.15199

- He, F. J., Wu, Y., Feng, X.-X., Ma, J., Ma, Y., Wang, H., Zhang, J., Yuan, J., Lin, C.-P., Nowson, C., & MacGregor, G. A. (2015). School based education programme to reduce salt intake in children and their families (School-EduSalt): cluster randomised controlled trial. BMJ: *British Medical Journal, 350*(mar18 13), h770–h770. https://doi.org/10.1136/bmj.h770
- Irwin, Speechley, M., Wilk, P., Clark, A. F., & Gilliland, J. A. (2019). Promoting healthy beverage consumption habits among elementary school children: results of the Healthy Kids Community Challenge "Water Does Wonders" interventions in London, Ontario. *Canadian Journal of Public Health*, 111(2), 257–268. https://doi.org/10.17269/s41997-019-00262-9

Kruitwagen - van de Gaar, V., Jansen, W., Grieken, A., Borsboom, G., Kremers, S., & Raat, H.
(2014). Effects of an intervention aimed at reducing the intake of sugar-sweetened
beverages in primary school children: A controlled trial. *The International Journal of*

Behavioral Nutrition and Physical Activity, 11(1), 98–98. https://doi.org/10.1186/s12966-014-0098-8

- Koch, Wolf, R. L., Trent, R. J., Ang, I. Y. H., Dallefeld, M., Tipton, E., Gray, H. L., Guerra, L.,
 & Di Noia, J. (2021). Wellness in the Schools: A Lunch Intervention Increases Fruit and
 Vegetable Consumption. *Nutrients, 13*(9), 3085–. https://doi.org/10.3390/nu13093085
- Lent, Vander Veur, S. S., McCoy, T. A., Wojtanowski, A. C., Sandoval, B., Sherman, S., Komaroff, E., & Foster, G. D. (2014). A randomized controlled study of a healthy corner store initiative on the purchases of urban, low-income youth. Obesity (Silver Spring, Md.), 22(12), 2494–2500. https://doi.org/10.1002/oby.20878
- Let's Eat Healthy. (n.d.). *4th grade Pre + Post Nutrition Assessments*. Let's Eat Healthy + Dairy Council of California . Retrieved October 30, 2022, from https://www.healthyeating.org/products-and-activities/curriculum/4th-grade/assessments
- Ma-Young Yeom, & Youn-Ok Cho. (2019). Nutrition education discouraging sugar intake results in higher nutrient density in diets of pre-school children. *Nutrition Research and Practice*, 13(5), 434–443.
- McCullough ML, Chantaprasopsuk S, Islami F, et al. Association of Socioeconomic and Geographic Factors With Diet Quality in US Adults. *JAMA Netw Open.* 2022;5(6):e2216406. doi:10.1001/jamanetworkopen.2022.16406
- Mikkilä, V., Räsänen, L., Raitakari, O., Pietinen, P., & Viikari, J. (2005). Consistent dietary patterns identified from childhood to adulthood: The Cardiovascular Risk in Young Finns Study. *British Journal of Nutrition*, 93(6), 923-931. doi:10.1079/BJN20051418
- Milwaukee Public Schools. (n.d.). District enrollment and Demographics. MPS. Retrieved March 27, 2022, from <u>https://mps.milwaukee.k12.wi.us/en/District/About-MPS/School-</u>

Board/Office-of-Accountability-Efficiency/Public-Items-Emjay/District-Enrollment.htm#:~:text=Currently%20Milwaukee%20Public%20Schools%20is,disability %2C%20and%20race%2Fethnicity.Enrollment.htm#:~:text=Currently%20Milwaukee%2 0Public%20Schools%20is,disability%2C%20and%20race%2Fethnicity.

- Nezami, B. T., Ward, D. S., Lytle, L. A., Ennett, S. T., & Tate, D. F. (2018). A mHealth randomized controlled trial to reduce sugar-sweetened beverage intake in preschool-aged children: Intervention to reduce sweetened beverages. *Pediatric Obesity*, 13(11), 668– 676. https://doi.org/10.1111/ijpo.12258
- Ogden C, Carroll M, Fryar C & Flegal K. Prevalence of obesity among adults and youth: United States, 2011–2014. NCHS data brief 2015(219):1–8. https://www.cdc.gov/nchs/data/databriefs/db219.pdf
- Public School Review. (n.d.). Milwaukee School District. Public School Review. Retrieved March 27, 2022, from https://www.publicschoolreview.com/wisconsin/milwaukeeschool-district/5509600-school-district
- Qualtrics (2022, August 29). Sample Size Calculator & Complete Guide in 2022. Qualtrics. Retrieved October 30, 2022, from https://www.qualtrics.com/blog/calculating-samplesize/
- RWJF. (2022, March 16). Pioneering ideas: Exploring the future to build a culture of health. Robert Wood Johnson Foundation. Retrieved December 3, 2022, from https://www.rwjf.org/en/library/funding-opportunities/2020/pioneering-ideas-2020exploring-the-future-to-build-a-culture-of-health.html

- Schieri, Paula Trotte, A., de Souza, R. A., & Veiga, G. V. (2009). School randomised trial on prevention of excessive weight gain by discouraging students from drinking sodas. *Public Health Nutrition*, 12(2), 197–202. https://doi.org/10.1017/S1368980008002644
- Stating the obvious: Writing assumptions, limitations, and delimitations. PhDStudent. (2021, May 3). Retrieved March 14, 2022, from https://www.phdstudent.com/thesis-anddissertation-survival/research-design/stating-the-obvious-writing-assumptionslimitations-and-delimitations/
- Taverno Ross, Barone Gibbs, B., Documet, P. I., & Pate, R. R. (2018). ANDALE Pittsburgh: results of a promotora-led, home-based intervention to promote a healthy weight in Latino preschool children. *BMC Public Health*, 18(1), 360–360. https://doi.org/10.1186/s12889-018-5266-3
- Te Velde, Wind, M., Perez-Roigo, C., Klepp, K. ., & Brug, J. (2008). Mothers' involvement in a school-based fruit and vegetable promotion intervention is associated with increased fruit and vegetable intakes - The Pro Children study. *The International Journal of Behavioral Nutrition and Physical Activity*, 5.
- Trude, Surkan, P. J., Cheskin, L. J., & Gittelsohn, J. (2018). A multilevel, multicomponent childhood obesity prevention group-randomized controlled trial improves healthier food purchasing and reduces sweet-snack consumption among low-income African-American youth. Nutrition Journal, 17(1), 96–96. https://doi.org/10.1186/s12937-018-0406-2
- University of Minnesota . (n.d.). *About NCC*. Nutrition Coordinating Center (NCC). Retrieved from http://www.ncc.umn.edu/

USDA. (2012, September). Serving Up MyPlate a Yummy Curriculum. USDA Food and Nurition Service. Retrieved from https://fnsprod.azureedge.us/sites/default/files/tn/sump_level2.pdf

USDA. (n.d.). *Kids' Corner*. Nutrition.gov U.S Department of Agriculture. Retrieved December 8, 2022, from https://www.nutrition.gov/topics/nutrition-life-stage/children/kids-corner

USDA. (n.d.). Recipes. MyPlate. Retrieved December 10, 2022, from

https://www.myplate.gov/myplate-

kitchen/recipes?search=kid&items_per_page=20&sort_bef_combine=search_api_relevan ce_DESC&prev_search=kid&sort_by=search_api_relevance&sort_order=DESC&page=

- US Department of Agriculture, Agricultural Research Service. (2020). Food Patterns Equivalents Intakes from Food: Mean Amounts Consumed per Individual, What We Eat in America, NHANES 2017-2018.
- U.S Department of Education. (n.d.). *Search for public schools*. National Center for Education Statistics (NCES) . Retrieved September 17, 2022, from https://nces.ed.gov/ccd/schoolsearch/school detail.asp?ID=550960001249
- Williams, K., & Dill , A. (2022, June). Nutritious, Delicious, Wisconsin. Wisconsin Department of Public Instruction. Retrieved from https://dpi.wi.gov/sites/default/files/imce/teamnutrition/pdf/nutritious-delicious-wisconsin-lessons.pdf

World Health Organization. (n.d.). *WHO calls on countries to reduce sugars intake among adults and children*. World Health Organization. Retrieved March 3, 2022, from https://www.who.int/news/item/04-03-2015-who-calls-on-countries-to-reduce-sugarsintake-among-adults-and-children

- Yang, Q., Zhang, Z., Gregg, E. W., Flanders, W. D., Merritt, R., & Hu, F. B. (2014). Added sugar intake and cardiovascular diseases mortality among US adults. *JAMA internal medicine*, 174(4), 516–524. https://doi.org/10.1001/jamainternmed.2013.13563
- Ziesmann, Kiflen, R., Rubeis, V. D., Smith, B. T., Maguire On Behalf Of The TARGet Kids Collaboration, J. L., Birken, C. S., & Anderson, L. N. (2019). The Association between Early Childhood and Later Childhood Sugar-Containing Beverage Intake: A Prospective Cohort Study. *Nutrients*, 11(10), 2338–. https://doi.org/10.3390/nu11102338
- Zhu, Z., Luo, C., Qu, S., Wei, X., Feng, J., Zhang, S., Wang, Y., & Su, J. (2021). Effects of School-Based Interventions on Reducing Sugar-Sweetened Beverage Consumption among Chinese Children and Adolescents. *Nutrients*, 13(6), 1862. https://doi.org/10.3390/nu13061862

Appendix

Appendix A Nutrition Education Program Curriculum and Schedule

Week 1:

- Completion of required forms, 24-hour diet recall data collection begins
- No nutrition education

Week 2:

- Completion of required forms, 24-hour diet recall data collection week continues
- No nutrition education

Week 3:

- Last week to complete 24-hour diet recalls
- Class 1
- Use curriculum from: "Lesson 1: MyPlate in My State" from Nutritious, Delicious, Wisconsin (Williams et al., 2022)
 - o Review MyPlate with visual
 - Discuss the 5 different food groups
 - Have students think about how their favorite meals fits MyPlate
 - o Discuss how Wisconsin farmers produce foods from each MyPlate food group
 - o Have students complete "Plate Activity Sheet"

Week 4:

No Class

Week 5:

- Class 2
- Use curriculum from: "Second Course" from Serving up MyPlate a Yummy Curriculum (USDA, 2012)
 - o Review what a nutrient is and its role in our body
 - Discuss how some nutrients can give us energy, have the class give examples of what we need energy for
 - o Discuss why eating a variety of foods from the different food groups is important
 - Discuss healthy snacks
 - Have the class complete the "Snack of Champions" worksheet

Week 6:

No Class

Week 7:

- Class 3
- Use curriculum from: "Lesson 4: Broccoli- A Nutrition Powerhouse" from Nutritious, Delicious, Wisconsin (Williams et al., 2022)
 - Review what nutrients are
 - o Review the 3 macronutrients and what they do for us
 - Review what vitamins and minerals are. Discuss how they do not provide us energy but have other roles that keep our body healthy and help us grow
 - Discuss the role of vitamin A, vitamin C, vitamin K, B vitamins, Calcium, and Potassium
 - o Discuss what Fiber is and what it does for us

Week 8:

No Class

Week 9:

- Class 4
- Use curriculum from: "Second Course" from Serving up MyPlate a Yummy Curriculum (USDA, 2012)
 - Create and print a sample MyPlate Daily Food Plan for a typical student. The food plan will show the amount of food students need from each food group each day
 - o Provide the class visuals of what a serving of each food group looks like
 - Show the kids what 1 oz of weight feels like using 5 quarters or 10 pennies, discuss how ½ cup of cooked pasta is equal to 1 oz
 - Have the class complete the "Measuring Up MyPlate" handout

Week 10:

No Class

Week 11:

- Class 5
 - Review key points from class 1-4 via PowerPoint, have students raise hands to answer questions
 - Play a class Kahoot game with questions from class 1-4 content

Week 12:

• No class (Fall break)

Week 13:

- Class 6
- Curriculum from the "Read the Label Youth Outreach Materials" by the U.S Food and Drug Administration (FDA, 2022)
 - Have the class watch the Making Healthy Choices Using the Nutrition Facts Label video
 - Go over the Nutrition Facts Label infographic with the class
 - Discuss how the kids can look at nutrition labels at convenience store, in the school lunch line and more to help them make healthier choices
 - Give the students the "Make Smart Choices" nutrition label word search handout to work on

Week 14:

No Class

Week 15:

- Class 7
- Use curriculum from: "Lesson 2: Parts of a Plant" from Nutritious, Delicious, Wisconsin (Williams et al., 2022)
 - Discuss the parts of a plant (seed, flower, fruit, stem, leaf, and root)
 - Explain the function of each plant part
 - Discuss how we eat the edible part of the plant
 - Give examples of what part of the plant different fruits/vegetables we eat are (A carrot is a root of the plant, broccoli is the flower of the plant, a tomato is the fruit of the plant etc.)
 - o Have students complete "Parts of a Plant Activity Sheet"

Week 16:

• No Class (Start of winter break)

• No Class (Winter break)

Week 17:

Week 18:

- Class 8
- Use curriculum from: "Lesson 3: Apples Around the World" from Nutritious, Delicious, Wisconsin (Williams et al., 2022)
 - Discuss the origin and history of apples
 - Have the students locate the Middle East and central Asia with you on the map, share with them that this is where apples first grew
 - Discuss some nutrients that are provided in apples (Fiber and vitamin C)
 - Review what vitamin C and fiber do for us
 - Do an apple taste test with the students and give them a small slice of each variety of apple
 - Have the students write down their opinion on each apple, have them pay attention to the taste, smell, and sounds when they chew it
 - Have the students vote on their favorite apple

Week 19:

No Class

Week 20:

- Class 9
- Use curriculum from: "Lesson 4: Broccoli- A Nutrition Powerhouse" from Nutritious, Delicious, Wisconsin (Williams et al., 2022)
 - Review how broccoli grows and what part of the plant it is
 - Discuss some of the nutrient's broccoli provides (vitamin C and vitamin K) and review what these nutrients do for us
 - Talk about different ways to eat broccoli (raw, steamed, roasted, added to dishes, etc.)
 - Review the nutrition label
 - o Have students complete the "Broccoli Nutrition Facts Activity Sheet"

Week 21:

No Class

Week 22:

- Class 10
- Use curriculum from: "Lesson 5: Carrots- All About Vitamin A" from Nutritious, Delicious, Wisconsin (Williams et al., 2022)
 - Review how carrots grow and what part of the plant it is
 - o Ask students what section of MyPlate do carrots belong in
 - Tell students some of the nutrients carrots provide (B vitamins and vitamin A)
 - o Review what these vitamins do for us
 - Discuss different ways you can eat carrots (boiled, steamed, baked into muffins, raw, roasted, grated in salads)
 - o Tell students what other sources of vitamin A are
 - Provide the students with a lunch menu and have them circle the different sources of vitamin A

Week 23:

No Class

Week 24:

- Class 11
- Use curriculum from: "Lesson 8: Milk from Cow to Table" from Nutritious, Delicious, Wisconsin (Williams et al., 2022)
 - Remind students what food group milk comes from
 - Ask students where milk comes from and then explain where milk comes if needed
 - Discuss how dairy farmers care for cows and the process of how the milk gets from the farm to our table
 - Ask the students if they have ever heard the word "pasteurized" before, explain what this means and why it is important
 - o Have the students complete the Milk from Cow to Table Matching Activity Sheet

Week 25:

No Class

Week 26:

- Class 12
 - Review key points from class 6-11 via PowerPoint, have students raise hands to answer questions
 - o Play a class Kahoot game with questions from class 6-11 content

Week 27:

No Class

Week 28:

- Class 13
- Use curriculum from: "Third Course" (First Taste) from Serving up MyPlate a Yummy Curriculum (USDA, 2012)
 - o Remind students that we need foods from all food groups
 - Discuss how some foods in each food group are healthier than others and we should eat these more often
 - Discuss how some foods should be eaten often, some foods should be eaten sometimes, and some foods should be eaten as a special treat
 - Go through examples of different foods with the students and have them pick if the food should be eaten "Often", "Sometimes" or as a "Special Treat"

Week 29:

No Class

Week 30:

- Class 14
- Use curriculum from: "Third Course" from Serving up MyPlate a Yummy Curriculum (USDA, 2012)
 - o Split the class into groups of 3-4 students
 - o Give each group the "Experiment: Added Sugars" handout
 - Have the students hypothesize how much added sugar is in each of the six beverages brought into class (12-oz can regular soda, 8-oz carton fat-free unflavored milk, 8-oz carton fat-free chocolate milk, 1 cup 100% orange juice, 1 cup lemonade, 1 cup water) and fill out the questions on the handout
 - Then as a class, go over the actual amount of sugar in each beverage, and discuss if their hypothesis was close to the actual amount
 - o Discuss healthier beverages students can choose instead
 - Discuss importance of hydration

Week 31:

• No Class (Spring Break)

Week 32:

- Class 15
- Use curriculum from: "Third Course" from Serving up MyPlate a Yummy Curriculum (USDA, 2012)
 - Split the class into groups of 3-4 students
 - o Give each group the "Experiment: Fats" handout
 - Have the students hypothesize how much fat is in each of the food items brought into class (three low-fat food items and three high-fat food items) and fill out the questions on the handout
 - Then as a class, go over the actual amount of fat in each food item, and discuss if their hypothesis was close to the actual amount
 - o Discuss how fat is an important nutrient, review its purpose
 - o Explain how there are some fats that are healthier than others, discuss

Week 34:

No Class

Week 35:

- Class 16
- Use curriculum from: "Lesson 9: A Nutritious, Delicious, World" from Nutritious, Delicious, Wisconsin (Williams et al., 2022)
 - Discuss common Wisconsin foods now
 - o Discuss traditional foods consumed by the American Indian tribes
 - o Discuss how people have immigrated to Wisconsin from all over the world
 - o Go through assorted breads and other grains from around the world
 - o Ask students about any foods or recipes that are special to their families.
 - Discuss with students how foods are associated with celebrations, traditions, and cultures.

Week 36:

No Class

Week 37:

- Class 17
 - Review key points from class 13-16 via PowerPoint, have students raise hands to answer questions
 - Play a class Kahoot game with questions from class 13-16 content

Week 38:

No Class

Week 39:

- 24-hour diet recall data collection begins
- Class 18 (Last Day)
 - o Bring in healthy snacks
 - Have a discussion with the students about what they took away from this nutrition education program
 - Pass out a piece of paper for the students to write anonymous feedback on
 - Play "MyPlate Grocery Store Bingo" (USDA, 2012)

Week 40:

• 24-hour diet recall data collection week continues

Week 41:

- · Last week of school
- Last week to complete 24-hour diet recalls

Appendix B Nutrition Class Summary Slip

Nutrition Class Summary Slip

Please ask your child to tell you one thing they learned at their nutrition education class this week, then review the class summary with them. Once completed, please sign this slip, date it, and have your child bring it to school to give to their nutrition education teacher.

Name:

Signature:

Date:

Appendix C Activities for Home

Options for Monthly Activities

Please complete at least one of the activities below at home each month. Have your parent/guardian sign one of the Monthly Nutrition Activity Slips that are in your nutrition binder once this is completed and bring the slip to class to give your nutrition education teacher.

- Play MyPlate Grocery Store Bingo
- Practice your fruit and vegetable knowledge using the Fruit and Vegetable Flash Cards
- Compete the MyPlate Word Banks "Cook off Craze" handout
- Complete the MyPlate Activity Sheet
- Complete the Parts of a Plant Activity Sheet
- Try a new recipe from MyPlate
- Try a vegetable you have not had before
- Try a fruit you have not had before
- Try a whole grain you have not had before
- Try eating a vegetable in a new way (steamed, roasted, added to a dish, etc.)
- Show a family member how to use the nutrition label

Appendix D Fruit and Vegetable Flash Cards (44 Cards)



(USDA, n.d)

Spinach

Aliases: None

Description: A dark-green leafy vegetable that can grow up to about 12 inches tall. Its leaves can be smooth, crinkly and curly, or slightly crinkly.

Wanted for: Its delicious leaves that are packed with vitamin A and also contain vitamin C, folate, and the mineral potassium. Fueling up on spinach helps kids eat smart to play hard.

Known Associates: Member of the Dark-Green Vegetable Subgroup.

Last Known Location: Spring and fall gardens where temperatures are cool. In some areas of the country, spinach can survive the winter and starts growing as the soil thaws. It is popular in salads, including salads served in the school cafeteria.

Notes: Recipes with "Florentine" in their name contain spinach, such as "Eggs Florentine."

Sweet Potato

Aliases: Sometimes mistaken for a yam (a starchy root that grows in Africa and Asia).

Description: This potato can have a light tan, orange, or purple skin. It can be a pale buff to deep orange color inside.

Wanted for: Its sweet root, which provides the mineral potassium, vitamins A and C, and fiber. Sweet potatoes are a delicious way to help make half your plate fruits and vegetables.

Known Associates: Member of the Red and Orange Vegetable Subgroup.

Last Known Location: Underground—dig it up in August through October. Also hangs out in supermarkets year round.

Notes: One large sweet potato equals 1 cup of veggies.

Sweet Corn

Aliases: Maize

Description: Usually yellow or white kernels attached to a cob.

Wanted for: Its seeds (the corn kernels). Corn helps kids eat smart to play hard.

Known Associates: Member of the Starchy Vegetable Subgroup.

Last Known Location: According to the 2007 Census of Agriculture (2009), sweet corn is harvested on over 28,000 farms and in all 50 States.

Notes: There is one strand of silk for each kernel of corn.

Leaf Lettuce

Aliases: Looseleaf, Oak Leaf, Red Leaf, and Green Leaf

Description: This lettuce does not form a head (like iceberg lettuce). Instead, its leaves attach at the stem. It can be yellow, green, red, reddish-bronze, or purplish.

Wanted for: Its crisp leaves, which give crunch to salads and sandwiches. The leaves provide vitamin A to help keep your eyes and skin healthy.

Known Associates: Member of the Dark-Green Vegetable Subgroup.

Last Known Location: In fall and summer gardens, leaf lettuce can go from seed to baby lettuce in just 3 to 4 weeks. Also found in salads everywhere.

Notes: High temperatures can make the leaves turn bitter in the garden.





INFORMATION FOR ADULTS A

With a variety of sights and smells, grocery shopping can be an exciting activity for kids. It can also be a little stressful for adults trying to buy groceries while keeping children entertained. MyPlate Grocery Store Bingo is a fun and educational activity that will focus the attention of your little ones while also allowing you to get your shopping done. That's what we like to call a "MyPlate, MyWin!"

AGES: 5 & UP

While most appropriate for elementary schoolaged children, this activity can be modified for other ages.

- For older children,
 For younger consider giving them their own shopping list so they can help you shop.
 - children, ask them to find foods of various colors and shapes.

INSTRUCTIONS:

- · Print off the bingo cards for kids accompanying you on a grocery shopping trip.
- Give them a pen or pencil and let them circle foods they see in the store while you shop.
- · Explain that we need foods from all five food groups.
- · Explain that fresh, frozen, and canned varieties all count.



Appendix F MyPlate Word Blanks



MyPlate Word Blanks "Cook-Off Craze"

How to play: Fold the paper in half so that the story is hidden. Read the Word Blanks below and fill in a word for each one. Match the numbered words from your word list with numbered blanks in the story. When you've finished, read your funny story out loud! You can also play with friends by writing down their choices for the word list, adding their words to the story, and then reading their special story to them.

WORD LIST

- Noun: _____
 Your name: _____
- 3. Friend's name:
- Verb (ending in "ing"): ______
- 5. Verb (ending in "ing"): _____
- 6. Green vegetable:
- 7. Noun (plural): _____
- 8. Noun (plural): _____
- 9. Color: _____

- 10. Orange/red vegetable:
- 11. Grain food: _____
- 12. Lean protein food: _____
- 13. Dairy food: _____
- 14. Noun (plural): _____
- 15. Adjective: _____
- 16. Fruit: _____
- 17. Verb (ending in "ing"): _____
- 18. Verb (past tense): _____

"Cook-Off Craze"

------ Fold Here ------

It was the end of the school year, and summer was just around the corner. It was almost time for the annual (1) _____County School End-of-Year Cook-Off! (2) _____and (3) _____entered themselves in the cook-off. They knew they had a good chance of winning if they used fresh veggies from Grandma and Grandpa's garden — the secret to their recipe! They were ready to start (4) _____!

Once they got the pot of water (5)	_, they began adding the ingredie	nts. While <u>(2)</u>
chopped up the <u>(6)</u> , <u>(3)</u>	washed the <u>(7)</u> .	<u>(8)</u> and
(9)cabbage were next. After this	s, they threw in some grated (10)	, going crazy
with all of their yummy fresh veggies! Making sur	e they didn't forget some grains, t	hey added some whole
wheat (11), and for protein power	, chopped <u>(12)</u> .	For a finishing touch, they
sprinkled some low-fat (13) on top	. Voilà! Summer Garden Soup!	

The day of the cook-o	off finally arrived and they were	ready. The event	was a huge success!
At the end of the day	, it came time for the group of (14)	to announce the
winners. After Runne	er-Up went to a <u>(15)</u>	(16)	frozen
yogurt, <u>(2)</u>	and <u>(3)</u>	_were <u>(17)</u>	their breath.
"And first place, with	the highest score, goes to (2)	and	<u>(3)</u> 's
Summer Garden Sou	p!!!" They were so happy that t	:hey <u>(18)</u>	all day long!



Word Blank #1

Appendix G MyPlate Activity Sheet



Williams et al., 2022)

Appendix H Parts of a Plant Activity Sheet

Parts of a Plant	
nstructions: List as many foods hat are grown in Wisconsin.	for each plant part as you can. Next, circle the foods
Plant Part	Fruits and Vegetables
Root	
Stem (or stalk)	
Leaves	
Flowers	
Fruit	
Seed	

Nutritious, Delicious, Wisconsin

(Williams et al., 2022)

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Appendix I Monthly Nutrition Activity Slip

Monthly Nutrition Activity Slip

Please fill out what suggested "Monthly Nutrition Activity" your child completed below. Then, sign/date this slip and have your child bring it to school to give to their nutrition education teacher.

ype of Activity Completed:	
lame:	
ignature:	
Date:	
Appendix J IRB Document



Mount Mary University Institutional Review Board (IRB) for the Protection of Human Subjects

Application for IRB Review

DATA COLLECTION CANNOT BEGIN UNTIL THE IRB HAS APPROVED THIS PROJECT

Directions:

- Faculty and student researchers, as well as student research advisors, should <u>read all relevant</u> information on the University IRB page in My Mount Mary before initiating an application. This includes full knowledge of the US Department of Health and Human Services Code of Federal Regulations Title 45 (Public Welfare), Part 46 (Protection of Human Subjects). http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.
- All applicants must verify completion of Human Subjects Training. See <u>http://www.citiprogram.org</u>.
- The IRB application must be filed and approved by the IRB prior to any Mount Mary University faculty, staff, or student (undergraduate or graduate), initiating a research project/study.
- If there is a cooperating institution, attach a copy of their IRB approval.
- In the case of a student research project, the student may complete the IRB application but the student's research advisor must sign and submit the application to the IRB for approval. It is the responsibility of the faculty research advisor to ensure that student applications and all attachments (e.g., informed consent forms and survey instruments) are in their final edited form. Even though a student research project may qualify as exempt from full IRB review, the research advisor may request the student to complete and submit a full IRB application.
- Complete this application using your word processing program (e.g. Word), then send it on or print it out and obtain signatures from all investigators and advisors. (Handwritten applications will not be accepted.) For your benefit, save the completed application on your computer in case it needs to be revised and resubmitted.
- This is a professional document; please check spelling, grammar and punctuation.
- Submit an electronic copy, via email, of the completed application with required signatures and attachments, in a single pdf, to Tammy Scheidegger, IRB Chair, <u>scheidet@mtmary.edu</u>. You will receive an email verifying receipt of the application.
- Allow a minimum of 30 working days to process your application. Make sure this timeframe is accounted for when considering initiation of data collection and due dates for student projects. Please be aware that if, upon completion of the application, you find that no exemptions apply to your research, your application will need to go through a full IRB Committee review which can take as many as 60 days to be completed.
- For class projects you must submit IRB applications to the IRB Chair by October 31st of the fall semester and March 31st for the spring semester. For summer classes, please consult with the IRB Chair.
- Upon receipt of the IRB letter of approval, data collection may begin.

I. <u>Required Documentation</u> - *No action will be taken without these attachments.*

Are the following attached to the IRB application?

Informed Consent Document	✔ Yes	Informed Consent Documents should include an explanation of procedures, risk, safeguards, freedom to withdraw, confidentiality, offer to answer inquiries, third party referral for concerns, signature and date. See Appendix A and use the MMU Informed Consent Template to avoid delays in the process.
Survey/Interview Instrument(s)	✔ Yes	If a survey is being administered in any written format (e.g., Google Forms, Survey Monkey, Qualtrics), a copy of that survey must accompany this application. If a survey/interview is being conducted verbally, a copy of the introductory protocol/comments and survey questions being asked must be attached to this application. If survey/interview includes focus group questions, a complete list of the question must be attached. For research using a published/purchased instrument, a photocopy of the instrument will suffice.
Verification of Human Subjects Training	🖌 Yes	Copy of transcript, certificate or other evidence that ALL members of the research team have completed the required training.
Copy of cooperating institution's IRB approval.	🖌 Yes	Not required if there is no cooperating institution.

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II. Investigator(s):	
Name: Catherine M Miosi	Phone: <u>262-391-9062</u>
Affiliation with Mount Mary University (e.g Email: miosic@mtmary.edu	g. faculty, student, etc.):
Signature:	Date: 9/4/22
Name:	Phone:
Affiliation with Mount Mary University: Email:	
Signature:	Date:
If student, list Research Advisor and com information and verify.	plete the application. Research Advisor must provide requested
Research Advisor's Name: Janine M. Bamb Email: <u>bambergj@mtmary.edu</u>	Phone: (414) 930-3264
Research Advisor: Have you completed Hun	man Subject's Training? 🗹 Yes 🗌 No
Research advisor's signature indicates responsibility for student compliance with all IRB requirements.	
Signature: Research Advisor	Date:

Individuals who participate in research play an important and active role in the advancement of knowledge. In recognition of their important contributions to research, humans will be referred to as "participants" rather than "subjects."

III. Project Description - Required by all applicants

Instructions: Briefly describe the proposed project including the sample and methodology (e.g. human subjects, data collection, data analysis and instruments).

1) Objectives (purpose of project):

The purpose of the project is to explore the difference in dietary intake, nutrition knowledge and food-related behaviors/attitudes between the students who participate in the nutrition education program and those who do not receive nutrition education.

2) Relevance to practice/body of knowledge:

While there have been studies on various nutrition education programs, relatively few studies have examined the effect of a comprehensive nutrition education program taught by dietitians to 4th grade students with familial/parental involvement

 Describe the research design (e.g. subject/participant selection and assignment, design, intervention, data analysis):

The study will be a randomized controlled trial. Twelve participating MPS schools will be included and within each school, 4th grade classrooms will be randomly selected as control or intervention groups. 24-hr diet recalls will be collected at the beginning and end of the school year for both groups.

4) What measurement/data collection tools are being used? The Nutrition Data System for Research (NDSR) dietary analysis software will be utilzed for analysis of the 24-hr diet recalls.

IV. Additional Project Information - Required by all applicants

1) What human subjects training has the researcher completed (e.g. course work, online certification)? N/A- Study will not be conducted

2) What process is used for obtaining informed consent? See Appendix A for consent content requirements and use the template, available on the MMU IRB webpage, when constructing your informed consent form. See below.

3) Does the research include special populations?

- Minors under 18 years of age?
- Persons legally incompetent?
- Prisoners?
- Pregnant women, if affected by research?
- Persons institutionalized?
- · Persons mentally incapacitated?

If <u>YES</u>, describe additional precautions included in the research procedures.

A research participant information and consent form will be provided and must be signed by the consenting parent. Students must sign an assent form after being provided information on the study.

4) Does the research involve any of the following procedures?

- False or misleading information to subjects?
- Withholds information such that their informed consent might be questioned?
- Uses procedures designed to modify the thinking, attitudes, feelings, or other aspects of the behavior of the subjects?

If <u>YES</u>, describe the rationale for using procedures, how the human subjects will be protected and what debriefing procedures are used.

Nutrition education courses provided in hopes to increase the level of nutrition-related knowledge of participants and increase the value they hold on a nutritious diet. The hopes is that the nutrition knowledge learned from this nutrition education program will translate to a positive change in nutrition-related behaviors. For example, consuming more vegetables and consuming less sugar.

✓ Yes	∐No
☐ Yes	✓No
🗌 Yes	✓No
🗌 Yes	✓No
☐ Yes	✓No
☐ Yes	✓No

Yes	✓ No
Yes	✔ No



5) Does the research involve measurement in any of the following areas?

- Sexual behaviors?
- Drug use?
- Illegal conduct?
- Use of alcohol?

If YES, describe additional precautions included in the research procedures.

N/A

Yes Yes	₽No
🗌 Yes	₽No
Yes Yes	₽No
Yes Yes	₽No

Yes No

Yes 🗹 No

☐ Yes ☑No ☐ Yes ☑No

6) Are any portions of the research being conducted online?

- Survey posted on a website?
- URL for survey includes information that could identify participants?
- Invitation to participate sent by email?Items use drop-down box?
 - If yes, assure that items allow choice of "no response"

If <u>YES</u>, to any of the above items, describe additional procedures. N/A

7) Describe the methods used to ensure confidentiality of data obtained.

All information obtained will be kept confidential by the researchers who will be the only people with access to the data. Information obtained will be stored electronically and will be password protected. Per the U.S. Office of Human Research Protections (code §46.115), all data will be destroyed 3 years after the end of data collection. Paper files will be shredded, and electronic files will be deleted. Individual participants will not be identified in any report or publication about this study.

Risks and Benefits

1) Describe risks to the subjects and the precautions that will be taken to minimize them. (Risk includes any potential or actual physical risk of discomfort, harassment, invasion of privacy, risk of physical activity, risk to dignity and self-respect, and psychological, emotional or behavioral risk.) No known risks.

2) Describe the benefits to subjects and/or society. (These will be balanced against risk.)

This research is designed to benefit the public health by providing resources to help improve dietary intake which can impact the health outcome. Although participants may not benefit personally from being in this research study, findings generated by this research may add new knowledge to the public health/nutrition field in general.

V. Is the proposed project "research" as defined by Institutional Review Board requirements? - <u>Required by all applicants</u>

Per 45 CRF 46.102: "Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes."

Per HHS.gov and the Office for Human Subjects Research (<u>https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html#:~:text=For%20purposes%20of%20the%202018,by%20a%20public%20health%20aut hority), the following activities are deemed <u>not</u> to be research:</u>

• Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

• Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

• Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

• Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

A human subject is defined as a living individual about whom an investigator obtains either 1) data through intervention or interaction with the individual; or 2) identifiable private information. In social science research, human subjects may be referred to as research subjects or research participants.

Does the research involve human subjects/participants or official records about human subjects/participants?

If "no", STOP here, and submit application.

If the results will be available in the library, presented at a professional conference (includes any presentation to group(s) outside of the classroom), or published, please check the Yes box:

Yes □No If "yes", proceed to SECTION VI. If "no, STOP here, and submit application.

VI. Exemptions - Required by all applicants

Are you requesting exemption from IRB review in one of the federally approved categories?

If yes, please reference OHRP website <u>http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</u> and continue with application.

1) Does the research meet the criteria for exempt category 1 (education)? [45 CFR 46.104(d)(1)]? Is the research conducted in established or commonly accepted educational settings (e.g. schools, Universities, or other sites where educational activities regularly occur)?

□Yes □No

□Yes □No

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Appendix K Consent Form



Title of Study: Intervention to Reduce Sugar-Intake and Improve Diet Quality in Children

Invitation to Participate and Purpose of the Research

You are invited to participate in a research study that seeks to determine the impact of a nutrition education program that will be implanted at your child's elementary school. The curriculum will contain topics such as the importance of a nutritious diet, building a balanced plate, the function of macronutrients and micronutrients in our body and more. Nutrition education will be delivered in 60-minute long bi-weekly sessions by the registered dietitian to the intervention students. Participants will be asked to complete four different dietary recalls both prior to and following the intervention. Data will be de-identified and analyzed by researchers.

Benefits and Risks

This research is designed to benefit public health by providing resources to help improve dietary intake which can impact the health outcome. Although participants may not benefit personally from being in this research study, findings generated by this research may add new knowledge to the public health/ nutrition field in general. There are no known potential risks associated with participating in this study. Please address any questions or issues of concern to the researchers using the contact information provided below.

Confidentiality

All information obtained will be kept confidential by the researchers who will be the only people with access to the data. Information obtained will be stored electronically and will be password protected. Per the U.S. Office of Human Research Protections (code §46.115), all data will be destroyed 3 years after the end of data collection. Paper files will be shredded, and electronic files will be deleted. Individual participants will not be identified in any report or publication about this study.

Contact Information

If you have questions about this research study, your rights as a research subject, or would like to know the outcome of the research, please contact [Dr. Tammy Scheidegger, IRB Chair and Catherine Miosi, Graduate Researcher)]. If you have any questions regarding your rights or privacy as a participant in this study, please contact Dr. Tammy Scheidegger, Mount Mary University Institutional Review Board Chair, 2900 North Menomonee River Parkway, Milwaukee, Wisconsin, 53222-4597, telephone (414) 930-3434 or email scheidet@mtmary.edu.

Consent

By signing below, you are indicating that you have read this consent form, have been given the opportunity to ask questions, and have agreed to voluntarily participate. You may withdraw from participation at any time, or refuse to answer any question herein, without penalty or loss of benefits to which other participants are entitled.

You may request a copy of this page for your records. Thank you for your participation.

Signature of participant	Date

Appendix L Child Assent Form



Child Assent Form

My name is Catherine Miosi. I am a student from Mount Mary University. I am doing a study to see if a nutrition class we will teach at your school is good at helping students make healthy food choices.

If you do the study, we will ask you at the beginning of the school year to answer questions about what you eat. At the end of the school year, we will ask you the same questions. We will not share your answers with anyone who is not working on the study.

We do not think any problems will happen to you if you are in this study. You might not like answering questions about what you ate. You can feel good about helping us to see if the nutrition lessons can help students make healthy food choices.

You do not have to be in this study if you do not want to. You can stop being in the study at any time. You can ask me or your teacher if you have any questions. My email is miosic@mtmary.edu.

Check one:

I want to be in the study. I do NOT want to be in the study.

Your Signature	Printed Name	Date
Name of Parent(s) or Legal C	Guardian(s)	
Researcher explaining study Signature	Printed Name	Date