Interventions to Promote Healthy Lifestyle and Academic Performance in Children During the Summer Months.

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Methods

Trial Design

This study is a three-armed quasi-experimental study employing a repeated measure within and between participant design comparing the HSL (n=60), to 21C (n=60), and no program (n=60). HSL is designed to mitigate academic learning loss and accelerated summer BMI gain by positively impacting children's obesogenic behaviors.

Participants

To distribute the costs of operating HSL the study takes place over two summers (i.e., June-August, 2018 & 2019). A single elementary school in the Columbia, SC metropolitan area will participate each summer (i.e., two schools, one each summer). Schools will be selected because they serve children from low-income households (100% free and reduced priced lunch) and they operate a 21C summer program. Inclusion criteria are that children are in the 2nd, 3rd, or 4th grade and their standardized reading score on the Measures of Academic Progress is between the 25th and the 75th percentile. Exclusion criteria is the presence of a severe intellectual disability (e.g., fragile X syndrome, severe autism). Measures of Academic Progress scores between the 25th and the 75th percentile and the absence of a severe intellectual disability were chosen as inclusion/exclusion criteria because these are the criteria the school district used to select children to participate in the 21C. A total of 90 students will participate each summer (i.e., 180 participants total). Participants will be assigned to one of three conditions HSL (n=60), 21C (n=60), or no program (n=60).

Interventions

HSL was designed in partnership with the local school district in which the study will occur. HSL was designed to, (1) address summer declines in reading achievement and (2) mitigate accelerated unhealthy weight gain during the summer by positively impacting children's obesogenic behaviors. HSL will operate at the participating schools and will be delivered by certified teachers. Participants enrolled in HSL will attended daily (Monday-Thursday, 8:00-15:30) for six weeks during the summer, with a one-week break in the middle of the program (i.e., 4th of July). The program day will consist of alternating sixty-minute periods of physical activity (3

total hours) with one hour and forty-five-minute periods of reading instruction (3.25 total hours). All participants will be provided a United States Department of Agriculture (USDA) Summer Feeding Program compliant breakfast (8:00-8:30), lunch (12:30-13:00), and a healthy snack. The USDA Summer Feeding Program mandates that foods align with the meal patterns laid out by this program. For breakfast this includes the provision of both fruits and vegetables and whole grain options and excluding sugar-sweetened milk beverages. In addition, breakfasts cannot exceed 500 kcal, 10% kcal from saturated fat, and 430 mg of sodium and lunches will not exceed 650 kcal, 10% kcal from saturated fat, and 640 mg of sodium. Lunches are required to include milk, fruits and/or vegetables, a grain, and a meat or meat alternative. For snacks the program could choose two of the four components of the lunch guidelines and had to include a fruit or vegetable. A 15-minute nutrition education session, based on the USDA Team Nutrition Curriculum [1], will be delivered by one of the teachers each day during lunch. The USDA Team Nutrition Curriculum focuses on eating a variety of low-fat foods and incorporating fruits, vegetables, and whole grains into children's diets daily. Nutrition Education sessions typically consisted of a 5-minute lesson by a certified teacher followed by a 10-minute activity session (e.g., activity sheets, comic book readings).

The 21C is a federally funded program providing academic enrichment opportunities for students who attend low-performing schools. Students enrolled in 21C will attend the same school as children enrolled in HSL. The 21C will operate daily (Monday-Thursday) from 8:30-14:00 for four weeks during the summer. The program day will consist of academic sessions in the morning and afternoon (9:00-11:30 & 12:30-13:45) and one hour of physical activity before lunch (11:30-12:30). All participants will be provided a USDA Summer Feeding Program compliant breakfast (8:30-9:00) and lunch (11:30-12:30). Children in the control will not attend either program.

Outcomes

For Body Mass Index Measures of Academic Progress Reading Scores and Cardiorespiratory Fitness baseline data collection will be conducted during the last month of the school year prior to the intervention summer.

Follow-up assessments will be conducted 3-months following baseline. For Physical Activity, Sleep, Screen Time, and Diet measures will be collected continuously from baseline to outcome.

Body Mass Index – Primary Outcome. Following standardized protocols trained research assistants will collect children's heights (nearest 0.1 cm) and weights (nearest 0.01 lbs.) without shoes in light clothing using a portable stadiometer (Model S100, Ayrton Corp., Prior Lake, Minn.) and digital scale (Healthometer model 500KL, Health o meter, McCook, Ill.). BMI will be calculated (BMI= kg/m^2) and transformed into age and sex specific z-scores (zBMI) according to the Centers for Disease Control growth charts [2].

Measures of Academic Progress Reading Scores – Primary Outcome. Children's reading achievement will be assessed via the MAP reading assessment. Created by the Northwest Evaluation Association (www.nwea.org), MAP results are widely accepted and used extensively in school-aged children [3]. Scores are reported using the Rasch Unit Scale, a curriculum scale developed using Item Response Theory that estimates student achievement. The Rasch Unit Scale ranges from 140-300 and are norm referenced based on grade [3]. MAP reading assessment will be administered as part of typical curriculum in the fall (first month of school) and end of the spring (last month of school) of each year.

Cardiorespiratory Fitness – Secondary Outcome. The Progressive Aerobic Cardiovascular Endurance Run (PACER) will be administered during regularly scheduled PE [4-10]. The PACER will be carried out by a trained research assistant and the PE teacher following standardized protocols on a marked outdoor green space.

Physical Activity & Sleep – Physical activity (MVPA, sedentary time) and sleep (total sleep duration, sleep onset, sleep offset, midpoint) will be measured using a Fitbit Charge 2™ (Fitbit Inc., San Francisco, California, USA). Fitbit Charge 2 devices have demonstrated initial reliability and validity for detecting heartrate and sleep [11-13]. Each Fitbit will be assigned a unique numeric identifier and each device will be linked to Fitabase (San Diego, CA, USA) a web-based interface that allows remote access and download of participants' second level

Fitbit data. Children will be asked to wear the Fitbit device every day for the entire summer (i.e., 12 weeks) starting the last week of school in the spring (May) until the first week of school in fall (August). Parents will be sent text reminders to sync and charge their child's Fitbit device every 3-4 days. Only days with >10 hours of waking wear [14] will be considered valid. Data processing will be informed by the ISCOLE data processing protocols [14].

Consistent with previous studies [15-18], daily resting heartrate for each child will be distilled into activity intensity levels by identifying the average of the lowest 10-mins beats-per-minute during wake time for each day. Resting heartrates above the 95th (90bpm), or below the 5th (50bpm) percentile will be considered implausible and replaced with the closest day that the child had a plausible resting heartrate. Percent heart rate reserve (HRR) will be calculated using the following formula $\frac{heart\ rate - resting\ heart\ rate}{maximum\ heart\ rate - resting\ heart\ rate}$ and will be used to determine activity intensity levels, with 0.0-19.9% of HRR as sedentary, and ≥50.0% as MVPA.[28-29] Maximum heart rate was defined as 197 beats per minute for all children [19]. Sleep will be identified and parsed from activity.

Sleep onset will be defined as the first minute that the sleep episode began. Sleep offset will be selected as the last minute that a sleep episode was recorded. The sum of the minutes that the Fitbit device classifies a child as asleep during a sleep episode will be considered total sleep time. Only nocturnal sleep will be considered for this study and will be defined as sleep onset that occurred between 5pm and 6am and lasted for greater than 240 minutes [20]. Sleep segments separated by less than 20 minutes will be considered one continuous sleep segment.

Screen Time and Diet

Parents will complete the following measures through an online survey that will be texted to their smartphone twice per week (i.e., one weekday and one weekend day) during the 12-week period that children wear the Fitbit device and will be encouraged to discuss their estimates with children to improve accuracy.

Parents will be asked to estimate the total amount of time (hours and minutes) their child spends in front of a screen taht day (e.g., TV, computer, video game, smartphone, and tablet).

Diet will be assessed via parent report food screener[21]. Items will be scored by four possible response categories and responses consist of the following: 0 (‘child did not consume’), 1 (‘child consumed a little’), 2 (‘child consumed some’), and 3 (‘child consumed a lot’) with those individual items. Individual food items will be grouped in accordance with the Healthy Meal Index (HMI) [22]. Food categories include; fruits, vegetables, dairy (non-sugar based), convenience foods, sweets and desserts and sugar sweetened beverages. Consumption will be dichotomized (i.e., ‘did’ vs. ‘did not’ consume) and reported as mean days/week [21]. Two variables will be created for analysis of diet; healthy foods/drinks (fruits, vegetables, and dairy), unhealthy foods/drinks (convenience foods, and sweets/desserts, sugar sweetened beverages).

Sample Size

The above selection criteria will yield 60 children in each arm of the study. Previous studies have shown that samples of 60-100 participants provide reliable estimates of statistical and recruitment parameters upon which subsequent large-scale trials can be based [23].

Randomization

A total of 180 children will be randomly selected to participate in the study. Of the 180 children, 60 will be enrolled in 21C program. Children will not randomly assigned to the 21C program as the participating school declined random assignment of these children. The remaining 120 (i.e., n=60 in 2018 and n=60 in 2019) will randomly allocated to one of two conditions HSL or control (no program) using a random number generator. Random assignment will be completed by the study principal investigator who will not be involved in data collection and will be completed each summer after participants enrolled in the study using the runiform command in Stata (v14.2, College Station, TX). Once implemented randomization cannot be changed.

Data Analysis

All analyses will be completed using Stata (v14.2, College Station, TX) with α levels set to $P < 0.05$. Data will be assessed for normality and descriptive statistics of programs, child characteristics, and outcome variables at baseline. The analyses will be estimated using an intent-to-treat approach [24, 25]. Multilevel mixed effects linear regressions with measures nested within children will be estimated. Separate models will be estimated for each dependent variable and included dummied group (control, HSL, 21C), time (baseline, post-summer, post schoolyear), and all group-x-time interactions. All analyses will include baseline scores on the dependent variable, age, gender, race, and year of participation as covariates in the models. Missing data will be handled using full information maximum likelihood estimates [26, 27]. The Benjamini-Hochenberg procedure with a false discovery rate of 10% will be utilized to account for multiple comparisons [28].

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