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Brief Title: Reducing Health Disparities in Childhood Obesity

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Methods

This randomized controlled trial was conducted during summer 2021, 2022, and 2023. The study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines. All procedures were approved by the Institutional Review Board of the University of South Carolina and the study was preregistered at Clinicaltrials.gov (NCT04072549).

Study Design and Participants.

We partnered with 7 Title I elementary schools from a single school district in a mid-sized metropolitan city in the southeastern United States that served 2,904 children from low-income families across the 3 years of the study. The average poverty rate at our partnering schools was 74% of the student population. In the spring (March-April) of each school year, we sent invitations to parents of children enrolled in kindergarten through 4th grade via each school's social worker, paper flyers, and electronic communications (i.e., online newsletter and Class Dojo). Recruitment materials were available in both English and Spanish. Children were eligible to participate if they were enrolled in one of our partner Title I schools, did not anticipate moving during the summer, and were able to complete the measures during the spring and summer (e.g., not out-of-state visiting relatives during the entire summer). Informed consent was obtained from one parent and/or guardian through an online Health Insurance Portability and Accountability Act (HIPAA)-compliant web-based survey platform accessed via a smartphone.

Randomization and Blinding.

Once parents completed the informed consent which confirmed their participation in the study and income proxy screener (i.e., public assistance services utilized and parent education), children were randomly allocated at a 1:1 ratio to either control (i.e., summer as usual) or intervention (i.e., free SDC), stratified by public assistance services used/received within family units, grade, and gender. Where parents had two or more eligible children, siblings were grouped together to ensure siblings were randomized to the same condition. Children were allowed to participate in the study for a single summer. Randomization occurred prior to baseline assessments each May. The decision to randomize at this time was made to treat the participating families with dignity and be respectful of their needs in making alternative summer care arrangements if their child was not randomized to receive free SDC. Randomization was performed by a co-investigator (R.G.W.) external to the day-to-day conduct of the trial using a stratified random number generator in STATA (StataCorp LLC, v.18.0). The lead investigator (M.W.B.) and data collectors were blinded to allocation.

Intervention and Control Conditions.

The intervention group was randomly assigned to receive 8 to 10 weeks of free SDC. The difference in the number of weeks was due to summer 2021 being shorter than summers 2022 and 2023 because of COVID-19 school closures. The SDC that served as the intervention was operated by a local parks and recreation commission, which operated multiple summer programs across the school district. The SDC provided indoor and outdoor opportunities for children to be physically active each day, included enrichment and academic programming, weekly field trips, and provided breakfast, lunch, and snacks. The foods served adhered to existing federal food program nutrition guidelines by the USDA and were reimbursed via the Summer Food Service Program (https://www.fns.usda.gov/summer/sunmeals). The SDC maintained a ratio of 1 staff member for every 12 children enrolled – consistent with childcare regulations. The SDC operated daily (Mon-Fri) for 8 to 10 weeks during the summer (except for the 4th of July holiday week). The SDC opened at 7am for morning drop-off and ended at 5pm each day. Based on the schedules of the SDC, physical activity opportunities were scheduled for 3 to 4 hours each day, with the remaining 4 to 5 hours dedicated to enrichment/academic content or field trips. An example menu and daily schedule are provided in Supplemental eFigure 1. The local parks and recreation commission had a history of operating SDCs in the community and had the appropriate safety and staff training certifications to ensure a safe/nurturing environment. Each summer a single SDC was provided for children to attend. The SDCs operated according to routine practice, with no outside assistance or modifications from the investigative team. In summer 2022 and 2023, the school district provided transportation for children assigned to the intervention group. No transportation was provided in 2021 due to COVID-19. The control group did not receive free SDC programming. These children experienced what we consider "summer as usual" (see Summer Programming Exposure below).

Measures

BMI z-score.

The primary outcome was change in age-sex specific BMI z-scores. Height (cm) and weight (kg) without shoes and excess clothing (e.g., jackets) were measured in triplicate as close to the end of the school year (right before summer vacation) in May and again upon return from summer at the start of the school year in mid-August. All measures were collected using research-grade stadiometer (HM 200P Portstad, Charder Eletrci Company, Ltd, Taiwan) and a digital scale (Digital Scale, MAXUS, China) by physical education teachers and trained research staff. Data collectors did not have any knowledge of group assignment when conducting the height and weight assessments. The original study was designed to assess BMI at the beginning of the school year (i.e., fall, August), the end of school year (i.e., spring, May), and again at the start of the next school year (i.e., fall, August). Unfortunately, the COVID-19 pandemic disrupted this timeline for 2021 where we had to forgo the three timepoints and only collect before (i.e., spring, May) and after summer (i.e., fall, August) BMI measures. Thus, what is present in this paper are the before summer and end of summer measurements of BMI.

Physical Activity and Sedentary Behaviors. Physical activity (PA) and time spent sedentary were measured using a wrist-placed accelerometry (ActiGraph GT9X) on the non-dominant wrist with a 24-hours wear protocol for 14-days.[1,2] The ActiGraph GT9X accelerometer is a triaxial research-grade accelerometer frequently used in studies measuring children's free-living 24-hour behaviors (i.e., PA, sedentary behavior, sleep). ActiGraph GT9X accelerometers were initialized and downloaded using Actilife software (version 6.13.4, ActiGraph LLC). Accelerometers were initialized to record data at a frequency of 30 Hz. Stop time was not used. Idle sleep mode was enabled to preserve battery life and the display was turned off to limit distractions for children while attending school.

Assessment of PA behaviors were collected at two timepoints each year – during school (April/May, average daylight 13hrs) and again during summer (mid-July, average daylight 14hrs). Children were instructed to wear the device during school and summer for 14 consecutive days during each assessment period. Devices were distributed and returned by mail. Each mailing contained a device and information regarding wear procedures (e.g., wear while awake and sleeping, waterproof). Data were downloaded and saved in raw format as .gt3x files and were processed using the GGIR package (version 2.8-2) in R (Version 4.1.2; R Foundation for Statistical Computing; Vienna, Austria). Time spent in PA intensity categories was determined using intensity thresholds described by Hildebrand et al.[3,4] A valid wear day was defined as a minimum of 16 hours and participants were included if they had at least one day of data.[5] The primary metrics of interest were time spent in MPVA and time spent sedentary in minutes per day.

Sleep. The amount of time (minutes per day) a child sleeps was collected via the wrist-placed ActiGraph on the non-dominant hand (described above).[6-8] This procedure has been validated as a measure of sleep and is used extensively in studies evaluating sleep.[7-11] The amount of time a child sleeps each night will was determined using two methods that are widely used in the sleep literature with children: 1) ActiGraph proprietary sleep algorithms to determine time spent sleeping, and 2) cross-referencing with parental/guardian report of time in bed and time of wake from the daily logbook.

Screen Time. Each evening of the 14-day accelerometer protocol, parents received a text via their smartphone to complete a time use record (see "Structured Program Exposure – Time Use Record" section below for details). One of the questions of the time use record asked parents to estimate the total amount of time (hours and minutes) their child spent in front of a screen that day (e.g., TV, computer, video game, smartphone, and tablet).

Food and Beverage Consumption. Children's food/beverage consumption was obtained via parent-reported daily diaries for 14 days during the spring (April/May) and 14 days during summer (July). Weekend days were excluded in analyses as the intervention was only delivered on weekdays. Within the daily diaries, parents completed a modified version of the 2009-2010 National Health and Nutritional Examination Survey (NHANES) Dietary Screener Questionnaire (DSQ).[12] The DSQ is a 26-item food frequency questionnaire in which parents report the frequency of foods/beverages consumed by their child each day, including fruits and vegetables, dairy/calcium, sugar-sweetened beverages, sweets/desserts, whole grains, red meat, and processed meat. For this study, questions on meat were excluded as there is no strong association between meat consumption and childhood obesity, while a question around snacks/chips was added to best reflect the diet of children.[13] Parents

were sent the daily diary at 8:00pm each day and were asked to complete this with their child to report on what their child ate and/or drank that day. Unlike the original screener, which asked respondents about consumption over the past 30 days (e.g., 1 time last month, 2 times per week), only response options referring to the frequency of consumption for that day were included (e.g., 1 time today, 2-3 times today) to capture day to day variation in consumption of each food/beverage component. For foods items, response options were “none”, “1 time per day”, and “2 or more times per day”. For beverages, the response options were “none”, “1 time per day”, “2-3 times per day”, “4-5 times per day”, and “6 or more times per day”. Procedures for assessing daily food/beverage consumption used in this study were similar to previous investigations with similar populations.[13] During analysis, response options were collapsed and recoded as did eat/consumed or did not eat/did not consume.

Child and Parent Demographics.

Each spring (April/May) parents completed a brief survey via their smartphone to collect information about the child (e.g., biological sex, parent self-identified race/ethnicity), household income, parent highest education level obtained, household food insecurity status, and the use/receipt of any of the following services: Welfare, Temporary Assistance for Needy Families (TANF), Temporary Cash Assistance (TCA), Children's Health Insurance Program (CHIP), Medicaid, Supplemental Nutrition Assistance Program (SNAP), Women, Infants and Children (WIC), or Supplemental Security Income (SSI).

Summer Programming Exposure.

We recognized that children randomized to the control condition (i.e., summer as usual) could voluntarily elect to enroll in some type of summer programming. Based on national data, we anticipated approximately 20% of the children randomized to the control would attend some type of summer programming.[14] Conversely, we recognized children randomized to receive free SDC could elect to not attend the free SDC or attend some other summer program offered. To account for differential exposure to summer programming in both the control and intervention groups, we collected information regarding summer programming attendance in three ways. First, at the beginning of summer (early June), parents completed a brief survey on their smartphone of the types of summer programming their child was anticipated to enroll in. Parents indicated the anticipated number of weeks enrolled in a program, the number of days per week the child was anticipated to attend, and whether the program was whole or half day. Second, on Friday of each week of the summer, parents received a text with a link to a brief survey about their child’s attendance in a summer program for that week. Parents indicated if their child attended a summer program that week and, if yes, on what days of the week they attended, and for how long each day. Third, during a 14-day period in mid-July, parents were texted each evening at 9PM and asked to complete a daily time use record. Each record took ~7min to complete. Parents indicated the places/locations their child went during the day and the times they were there. Completed time use records for weekdays (the days when a child could attend a summer program) were used to estimate summer program exposure.

Statistical Power.

Sample size calculations were based on the ability to detect a statistically significant group (intervention vs control) by time (before summer to end of summer) difference in the change in zBMI with a mixed-effects model with statistical power of 0.80 and an alpha of 0.05. Estimates from the largest and most recent studies [15-17] conducted to date reported the average change in zBMI during the summer ranged from 0.04 to 0.09, and the average change in zBMI during the school year was -0.02. Accounting for the intraclass correlation at the school level [18] and an anticipated attrition rate of 25%, the total number of children required to be enrolled at baseline was 420 to arrive at a final sample of 330 (165 per condition).

Statistical Analyses.

BMI. The primary analysis was intent-to-treat (ITT), defined as using all available data from children according to the original group they were randomized (free summer day camp or continue summer as usual) regardless of their attendance at a summer program. Analyses used mixed-effects models, accounting for the nesting of repeated measures within children, families (i.e., siblings), and schools. The treatment effect of interest was the group (intervention vs control) and time (pre summer vs post summer) interaction. Missing data on the primary outcome (zBMI) was accounted for using full information maximum likelihood estimation, allowing for all children’s zBMI data to be used regardless of missing zBMI at either pre or post summer. Covariates included in

the model were the child's baseline zBMI, biological sex [19] and age,[20] self-reported race/ethnicity,[21] parent education,[22] food insecurity status,[23] and poverty level.[24] Missing data on covariates were handled using multivariate multiple imputation of 100 datasets for both continuous and categorical covariates using STATA v18.0 multiple imputation commands. Secondary analyses examined the dose-response of summer program attendance including both the intervention and control groups. These models used each of the three summer program exposure metrics as continuous independent variables (standardized to the percentage of days attended during the week), to examine the impact of the amount of summer programming on changes in zBMI. The assumptions for all models were checked using plots of the estimated residuals, no violations were found.

MVPA, Screen Time, Sleep. The primary analysis was intent-to-treat (ITT), defined as using all available data from children according to the original group they were randomized (free summer day camp or summer as usual) regardless of their attendance at a summer program (e.g., intervention children never attending the SDC and control children attending some other form of SDC). Analyses used mixed-effects models, accounting for the nesting of repeated measures within children, families, and schools. The treatment effect of interest was the group (intervention vs control) and time (pre summer vs post summer) interaction. Missing data on the dependent variables of interest of MVPA, time spent sedentary, sleep, and screen time were accounted for using full information maximum likelihood estimation,[25] allowing for all children's data to be used regardless of missing data at either pre or post summer. Covariates included in the model were the child's biological sex[19] and age,[20] self-reported race/ethnicity,[21] parent education,[22] food insecurity status,[23] and poverty level.[24] Missing data on covariates were handled using multivariate multiple imputation with the covariates serving as variables to inform the imputation of 100 datasets for both continuous and categorical covariates using STATA v18.0 multiple imputation commands.

Secondary analyses (i.e., exposure models) examined the exposure to structured programing and included both the intervention and control groups. For these analyses we defined exposure to structure as any day where a child is reported on the TUR to have attended a structured setting outside the home (attended/not attend, binary variable). This choice of dichotomizing structured settings at the day level was done because the distribution of minutes in a structured setting was heavily skewed in the summer. Children (both intervention and control), when they were reported to have attended a structured setting in the summer, did so for a day-long program (i.e., 7-8hrs), which for the intervention group was the typical length of attending the SDC. This means that for the children in the control group, when they did attend structured programming in the summer, this programming lasted for approximately the same length of time as the intervention group. Because all children were exposed to school, exposure to structured programming during school (April/May) excluded attending school and, therefore, represents only additional structured programming a child was exposed to above and beyond the school day. In addition to changes in the continuous outcomes, we examined the probability of meeting MVPA (≥60 minutes per day) and screen time (≤120 minutes per day) guidelines[26] using both the above stated ITT and exposure to structured programming models. All models included both weekdays and weekend days. Because free SDC was provided on weekdays only, we also conducted the same ITT and exposure analysis restricting the data to only weekdays. The assumptions for all models (normality of residuals, homoscedasticity) were checked using; no violations were found. All models were conducted using STATA v18.0 (College Station, Texas).

Diet. The primary analysis was intent-to-treat (ITT), defined as using all available data from children according to the original group they were randomized to (free SDC or summer as usual) regardless of their parent-reported attendance at a summer program.[27] Mixed effects models were used to account for the nesting of repeated daily measures within children. The analyses examined the odds of consuming different foods/beverages during weekdays in the summer, controlling for school year endorsement of consuming that food or beverage, in the free SDC group compared to summer as usual. During analysis, day-level food/beverage response options (e.g., 1 time today, 2-3 times today) were collapsed and recoded as binary values: 1 = consumed and 0 = did not consume. Analyses excluded weekend days as the intervention was only delivered on weekdays. Missing data for outcome variables were accounted for using full information maximum likelihood estimation, allowing for all children's data to be used regardless of missing data. Covariates included child biological sex, parent education, food security status, the use of assistance services (e.g., SNAP, WIC), and income. Missing data for covariates was handled using multiple imputation of 100 datasets for both continuous and categorical covariates.

Secondary analyses were as-treated, defined as using all available data from children based on their parent-reported attendance at a structured program on weekdays in the summer, regardless of what group they were randomly assigned to.[28] This analysis examined the impact of attending structured summer programming, both

as a binary predictor (days children attended vs days not attended) and as categorical minutes attended (30-239min/d or ≥240min/d vs did not attend “zero” minutes [reference group]) on the odds of consuming different food/beverages during weekdays in the summer, controlling for consumption during the school year and all covariates included in the primary analysis. The 30-239min/d grouping corresponds to half-day or shorter programs, while ≥240min/d corresponds to longer than half-day up to full-day programs. The assumptions for all models were evaluated by examining multicollinearity, residual plots, and the distribution of random effects; no violations were found. STATAv17.0 was used to run all statistical analyses

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