Title: Preventing Weight Gain and Unhealthy Behaviors in Children

08/08/2019

Rigor and Transparency. The proposed study is designed to rigorously evaluate the effect of providing access to structured programs during the summer on children's unhealthy weight gain, fitness loss, and the obesogenic behaviors that underlie these effects. Specific examples of the rigor of this study include randomizing children following baseline measurement, using measures shown to produce valid and reliable data in the study population, completion of a power analysis, appropriate statistical analyses, properly controlled design, and blinding staff handling the data to study condition. These methods will allow for the proposed study to produce robust and unbiased results.

D1. Theoretical/Conceptual Framework - Structured Days Hypothesis. This study hypothesizes that summer camps will provide structure during the summer that will reduce children's obesogenic behaviors. Mechanisms driving reduced obesogenic behaviors on structured days are detailed in **Figure D1** below.

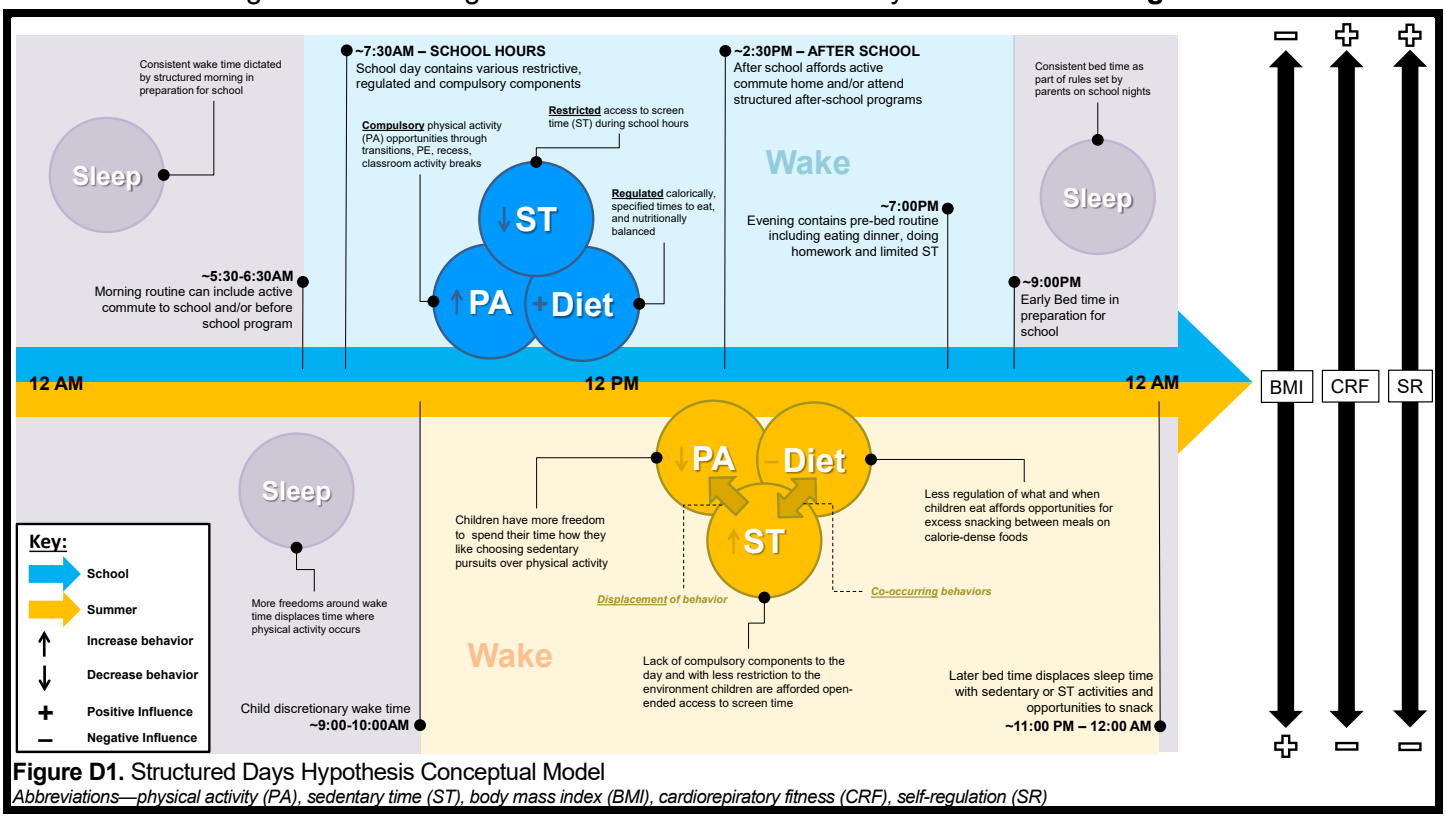

Figure D1. Structured Days Hypothesis Conceptual Model
Abbreviations—physical activity (PA), sedentary time (ST), body mass index (BMI), cardiorepiratory fitness (CRF), self-regulation (SR)

D2. Hypotheses.

Aim 1 (Primary): It is *hypothesized* that **A)** children randomized to attend the summer day camp will experience minimal gain in zBMI and loss of fitness during the summer that they receive summer camp access; **B)** children will experience accelerated weight gain and fitness loss during the summer they are randomized to not receive summer camp access and that **C)** all children will experience similar weight loss and fitness gain during the school year due to the restrictive, compulsory, and regulatory components of school.

Aim 2 (Secondary): It is *hypothesized* that **A)** children randomized to attend the camp will engage in fewer obesogenic behaviors during the summer that they attend the camp than their peers during the summer they do not attend camp, and that **B)** all children will engage in fewer and similar levels of obesogenic behaviors during the school year due to the restrictive, compulsory, and regulatory components of school.

Aim 3 (Exploratory): It is of interest to explore: **A)** if children randomized to attend the camp will experience increases in self-regulation while their peers who do not attend the camp will experience decreases in self-regulation, and if **B)** self-regulation at the beginning of summer will moderate unhealthy changes in weight and fitness at the end of the summer for those children who do not attend the summer camp.

D3. Study Design. The study will be a randomized controlled trial. To distribute costs over years, the study will recruit two cohorts of 1st and 3rd grade students. The first cohort will be recruited in Y01 and the second will be recruited in Y02. Following baseline data collection, children in each cohort will be randomly assigned to either the treatment or control. The sample of students recruited in the 1st grade will be observed during the summer after their 1st grade year and the school year when they are in the 2nd grade. Students recruited from the 3rd grade will be observed in the summer following their 3rd grade year and the school year during 4th grade.

D4. Study Population and Recruitment. Procedures for sampling children are detailed in Clin-Trls Section 2, Recruitment and Retention Plan. Briefly, the Recreation Commission operates 11 summer day camps located

at parks. Each camp serves ~100 children every summer. To draw a sample of children, 5 summer camps that operate in the catchment area of elementary schools where ≥90% (range = 90%, 100%) of children enrolled are eligible for free and reduced lunch have been identified. A total of 2,333 children (49% female) attend these schools. Children attending the identified schools will be stratified by gender and grade level. In Y01 and Y02, 40 (i.e.,80 total) randomly identified children will be invited to participate in the study.

D5. Intervention to be Tested. A detailed description of the intervention to be tested can be found in Clin-Trls Section 4, Narrative Study Description and Interventions. Briefly, children in the study will be randomly identified to take part in the Voucher Program. During the summer, children in the Voucher Program will receive a voucher that covers enrollment fees associated with accessing a day camp operated at a park near their school. The total value of the voucher for a single child for an 8-week summer will be $880 ($110 per week). This fee covers all operating expenses plus transportation to and from the camp. The summer day camps (defined in **Section A5)** will be existing summer day camps operated by the Recreation Commission. The summer day camps provide indoor and outdoor opportunities for children to be physically active each day, provide enrichment and academic programming, as well as breakfast, lunch, and snacks. Importantly, these camps are enrolled in the USDA Summer Food Service Program. Thus, all meals adhere to the Summer Food Service Program nutrition guidelines. The camps employ 1 staff member for every 12 children and operate daily (Mon-Fri) for the entire summer. The camps open at 7am and close at 6 pm daily. Physical activity opportunities are scheduled for 3 to 4 hours each day, with the remaining 4 to 5 hours dedicated to enrichment or meals/snacks. These camps will operate according to routine practice, with no outside assistance from the investigative team. Children randomly assigned to the control group will be enrolled in the same schools as those randomized to receive the Voucher Program. The comparison/control group will not receive a voucher to attend a summer camp. It is possible that children serving in the control/comparison condition may elect to voluntarily participate in a summer program. However, based on enrollment numbers from pilot work (see **Section C**), the limited number of weeks children were enrolled (avg. of 2 weeks), the associated costs of enrolling (i.e., $880 per child), and national data indicating that few children from low-income families attend summer day camps (see **Section A5**), it is unlikely that comparison/control children will enroll in a summer day camp. Thus, there is a high degree of confidence that the comparison/control group will represent weight and fitness outcomes associated with children not attending a summer program.

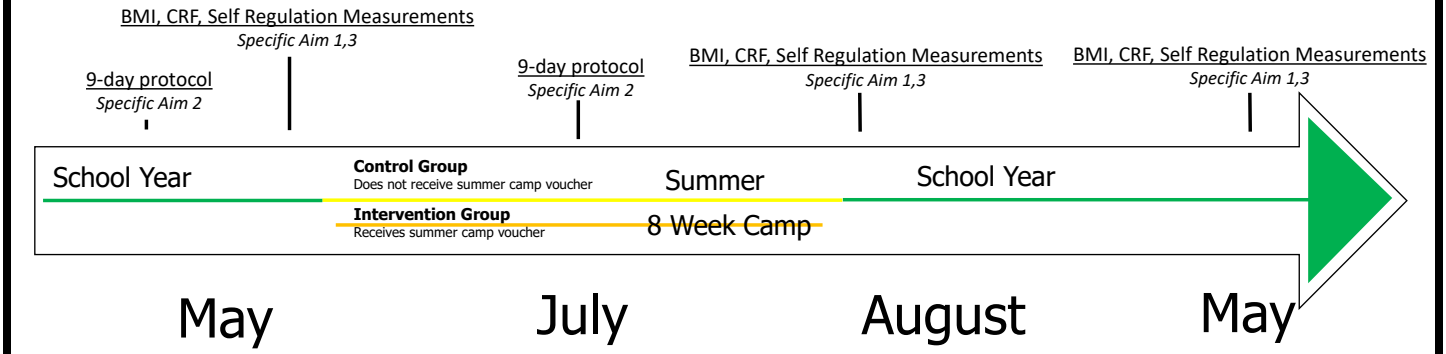

Figure D6. Schedule of school year and summer measurements
Abbreviations—body mass index (BMI), cardiorepiratory fitness (CRF)

D6. Primary and Secondary Measures. Details for implementation of the measurement plan will be finalized in consultation with the CTL Core with respect to training of data collectors, record-keeping procedures, data capture procedures, and construct scoring. For a detailed description of the primary, secondary, covariate, predictor, and determinant measures see Clin-Trls Section 4, Narrative Study Description and Outcome Measures. All measures were selected in consultation with our consultants, the participating school district, and the Recreation Commission. The measures selected 1) represent state-of-the-art techniques that are known to produce valid and reliable data and 2) minimize burden on the participating families.

D6.1. Primary Outcomes (Specific Aim 1). All students enrolled in the study will take part in a cardiovascular fitness (CRF) test (i.e., PACER)[2-8] and have their height and weight measured by trained research staff using standard procedures during a regularly scheduled physical education class. This information will be used to compare changes in BMI (translated into age-sex z-scores [zBMI]) and CRF during summer and the school year. The tests are valid and reliable and used extensively with the proposed age groups.[59-63] Peak height velocity will also be collected as a marker of biological maturation (covariate in statistical models).[1]

D6.2. Secondary Outcomes (Specific Aim 2). Briefly, physical activity, sedentary behaviors, and sleep will be collected using a non-dominant wrist-placed ActiGraph Link for 9-days (common timeframe to collect physical

activity data).[45, 64-74] Children's screen time will be assessed using a parent-proxy report measure completed daily for 9 days by the parent with their child. Parents/children will estimate the total amount of time (hours and minutes) spent in front of a screen that day (e.g., TV, computer, video-game, smartphone, and tablet). [75] Dietary behavior of participants will be estimated using several dietary screeners that have been found to be valid and reliable when compared to multiple pass dietary recall.[76-90]

Table D6. Description of Measures for Primary and Secondary Outcomes and Exploratory Variables at the Child Level

Outcome	Construct	Assessment/Tool	Description/Protocol
Primary	**BMI z-score (zBMI)**	Height and Weight	Height (cm), weight (kg) w/out shoes or heavy clothing. **See Section D6.1.**for details
Primary	**Cardiorespiratory Fitness**	PACER	FITNESSGRAM standardized protocol. **See Section D6.1.** for details
Secondary	**Physical Activity**	Accelerometry	Physical Activity (ys). **See Section D6.2.** for details
Secondary	**Sedentary Behaviors**	Accelerometry	Sedentary Activity (9-days). See **Section D6.2.** for details
Secondary	**Sleep**	Accelerometry	Sleep Activity (9-days). See **Section D6.2.**for details
		Daily Diary	Daily diary (9-days) completed in evening with help of child (when necessary) report of bed time and wake – See Appendix for details.
Secondary	**Dietary Intake**	Child Intake of Food/Beverage	Parent report of child past week food/bev intake. See **Section D6.2.**
Exploratory	**Self-regulation (child report)**	COMPSCALE – Short Form	The COMPSCALE short form is a 18-item rating scale adapted from the COMPSCALE for children to self-report motives and behavioral inclinations that are linked to socially competence and self-regulation. **See Section D6.3.**
Exploratory	**Self-regulation (classroom teacher and parent report)**	COMPSCALE	The COMPSCALE is a 35-item rating scale that adults complete about children. It measures motives and behavioral inclinations that are linked to socially competent and self-regulated children. **See Section D6.3.**

D6.3. Covariate, Predictor, and Determinant Measures. Participant self regulation will be reported by the classroom teacher and parent/guardian of each child prior to and following each summer.[91] Children will also complete a similar COMPSCALE – Short Form, an 18-item survey that rates their ability to self-regulate.[92] The parent/guardian of each child will also complete a survey that covers rules for bedtime, the home food environment, social support for physical activity, and child dietary intake. Survey questions are from established surveys used to investigate the influence of parents on the health behaviors of their children. To account for environmental factors associated with accelerated weight gain or fitness loss, the obesogenic nature of participating children's/families' neighborhood environments will be assessed using measures that are consistent with other recent, large-scale studies of environmental influences on physical activity and nutrition.[93-96] These measures include walkability (e.g., net residential density, intersection density, land use mix, and retail floor area ratio),[97] the number of parks (and total park acreage) and the number of public (e.g., municipal community center), non-profit (e.g., YMCA), and private (e.g., indoor soccer complex) recreation facilities using publicly-available sources,[93, 94] crime data,[98, 99] neighborhood food,[93, 94, 96] and neighborhood-level disadvantage.[100]

D6.4. Process Implementation Outcomes. Detailed process/implementation data will be captured. Specifically, for each child randomized to the Voucher Program or the comparison/control group, information regarding their attendance at a summer day camp will be collected. For the Voucher Program group in the summer of Y01 and Y02, detailed information will be collected regarding the programmatic offerings occurring at the camps, [101-108] and types of foods and beverages served.[109-112]

D7. Protocol for School and Summer Data Collection. This section describes the protocols for administering the FITNESSGRAM assessments, both H&W and PACER, over a 9-day period during the school year and summer. During the school year children will run the PACER and have their H&W collected during physical education class prior to and following each summer. During this class children will also be provided the activity monitors (ActiGraph), and surveys to take home to their parent for completion. For summer, H&W and PACER will not be collected (see Figure D6.) but monitors and surveys will be distributed during scheduled family days at the child's elementary school (see below for details). During summer and the school year, the parent/guardian will receive text prompts with daily reminders to complete the survey instruments during the 9-day assessment. For the summer, parents/guardians and their child will be contacted in one of two ways. The first primary contact will be through a day-long (8am-5pm) open house at their child's school. Parents/guardians of children participating in the study will be texted two weeks and one week prior about attending a Saturday open house. Parents/guardians showing up to the in-person summer open house will receive $50 when returning the devices and completed survey packet.

D8. Power Considerations, Statistical Design, and Missing Data. The SDM Core assisted the PI with respect to the analytic plan described in this application. The SDM Core will assist the research team with the codebook (for raw data and constructs), specification of missing data flagging and procedures, data entry/capture, data management, preliminary examination of distributions in preparation for analyses, conduct of statistical analyses, and assistance in interpretation of programming output. All analyses will be completed by the SDM Core, which will have individuals with extensive expertise in the statistical models required for

analyzing the data collected in the proposed project.

D8.1. Power Considerations. Details of the power analysis completed for this study are presented in Clin-Trls Section 4, Statistical Power and Design. Based on the hypothesized difference between z-BMI change for children who receive and do not receive a voucher (i.e., 0.22 vs. 0.11) this study is sufficiently powered.

D8.2. Statistical Models. To test the hypothesis in **Aim 1** and **Aim 2**, repeated measures linear and non-linear mixed models accounting for repeated measures within children and children within schools will be estimated. Group, time, setting (i.e., school vs. summer) and all 2-way and 3-way interactions will be included, with the group-x-time-x-setting interaction as the primary contrast of interest. Structural equation models will also estimate the mediating pathways of the obesogenic behaviors on zBMI change.

D8.3. Sex as a Biological Variable. Because girls and boys have been shown to engage in differing levels of obesogenic behaviors and to have differing levels of fitness and prevalence of overweight and obesity, all models will include sex (i.e., boys vs. girls) and age as covariates. Including sex as a covariate in models will preserve the statistical power of the study while allowing for the examination of sex as a biological variable.

D9. Group Assignment. The unit of randomization will be at the child level. The two conditions will be: 1) Intervention - children receiving a voucher for a summer day camp and 2) Control - no summer day camp voucher. Children will be randomized (using a random number generator) by stratifying them based on grade and gender to ensure equal numbers across the age range and boys and girls in each of the two conditions.

D10. Timeline. A project timeline is provided in Clin-Trls Section 2, Extended Study Timeline.

D11. Limitations and Benchmarks of Success. One key to success will be the study retention of children/families over time. To address this, the measures have been modified based on piloting with comparable individuals and incentives are planned for participation. Another key issue is whether children receiving vouchers attend the day camp during the designated summer. Children in the intervention condition who fail to attend the camp would obviously not be exposed to the independent variable. However, the Recreation Commission has observed that high community demand for summer programming, coupled with ease of access because the camp is centrally located, makes attendance likely. Further, camp attendance (and lack thereof) will be tracked to explore possible barriers to attendance.

D12. Transition to R01-level Grant Submission. The knowledge gleaned from this study will be invaluable to the development or enhancement of existing systems and interventions that support both the physical (weight and fitness), social, and emotional wellbeing children. The study results will provide a foundation for an R01-level grant submission expanding this line of research on interrupting unhealthy weight gain and fitness loss during the summer and continuing to build a foundation for promoting self-regulation to influence both physical health and social-emotional development. This study also has the potential to interrupt a long unstructured period (i.e., summer) in children from low-income households. This could be crucial for helping these children develop self-regulation that could lead to better social, emotional, and behavioral adjustment. The preliminary evidence produced by this study will justify an R01-level study to test the Voucher Program in a large-scale RCT. Should the Voucher Program prove ineffective, this preliminary study will yield detailed process information to inform additional intervention targets for summer programming (e.g., self-regulation). The proposed study will be one of the first to measure self-regulation in addition to all four obesogenic behaviors on the same children during the school year and summer break. Not all of the behaviors in all the children will change in a similar fashion. This study provides initial evidence to suggest patterns of behavior change in groups of children. For instance, activity might substantially decrease in some children without concomitant changes in sleep, diet, or screen time. Other children might show change in more than one of these behaviors, which might nullify the detrimental changes in the other behaviors or interact in unforeseen ways. Further, this study has the potential to produce preliminary data related to the moderating effect of self-regulation on these behavioral pathways. Should self-regulation prove critical, the R01 will incorporate more explicit strategies for targeting self-regulation and more scientifically rigorous measures of the construct. Without this evidence, efforts to mitigate summer weight gain could be misguided, wasteful of resources by unnecessarily targeting all behaviors simultaneously, and less effective than more planned/targeted approaches. Thus, even under conditions of null results, it will be possible to develop more effective strategies for reducing unhealthy weight gains and fitness loss to test in a rigorous well-powered R01