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SOCIAL, BEHAVIORAL, and NON-CLINICAL RESEARCH PLAN

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Please complete: CPHS# 31225 PI: Diane Gilbert-Diamond, ScD

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1. Introduction and Background

In the Children's multimedia study, we propose to investigate the effects of media multi-tasking on child obesity. The modern obesogenic environment is replete with cues to eat. Environmental food cues stimulate brain reward regions and lead to excess consumption independent of hunger levels (1). This cued eating is partially mediated by the amount of attention given to food cues. For example, children who spend more time looking at food cues consume more calories than children who do not (2). We propose that the prevalent practice of media multi-tasking—simultaneously attending to multiple electronic media sources—increases attention to peripheral food cues and subsequent cued eating and thereby plays an important role in the development of obesity. Neural networks are responsible for controlling attention to peripheral cues. The dorsal and ventral orienting networks control the shifting and focusing of attention, and the frontoparietal network controls the filtering of peripheral cues in the environment (3-5). Media multi-tasking is known to increase orienting and decrease the filtering abilities associated with these networks (6-8). By this mechanism, we propose that media multi-tasking increases obesity risk by increasing attention to peripheral food cues. Current efforts to address obesity ignore this prevalent risk behavior. Fortunately, it is possible to improve the functioning of the attentional networks through attention modification training (9); thus this research examines the hypothesis that attention modification training can decrease the amount of attention children give to food cues.

Theoretical Model

We propose that the persistence of childhood obesity (Figure 1) is caused, in part, by the rise in media multi-tasking that alters attention to peripheral cues, rendering some children more susceptible to cued eating. We expect that high levels of media multi-tasking weakens the attentional network responsible for filtering out distracting environmental cues (frontoparietal network) and strengthens the attentional networks responsible for shifting and focusing attention to peripheral cues (ventral and dorsal orienting attentional networks) (3-5). We theorize that by altering these attentional networks, media multi-tasking renders children particularly susceptible to food cues, thereby leading to cued eating. The functioning of attentional networks can be modified through attentional training that improves sustain attention, which we expect can provide a protective effect against overeating by decreasing attention to food cues.

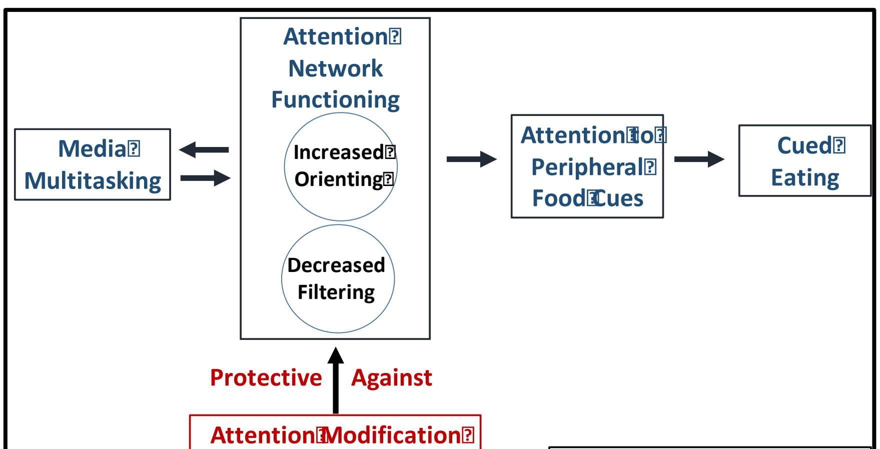

Figure 1: Theoretical Model

Media multi-tasking is an increasingly prevalent exposure that may have important public health consequences.

Children's ownership of diverse media devices is increasing. For example, ownership of a cell phone went from fewer than 40% of children in 2004 to 66% by 2009, and the use of iPods/MP3 players increased from 18% to 76% during that period (14). With this rise in device ownership is a concurrent rise in media multi-tasking; from 1999 to 2009 children nearly doubled their time spent media multi-tasking, from 16% of the time to 29% of the time that they were using media (14). Critically, this trend shows no signs of slowing. From 2011 to 2013, children's access to mobile devices increased from 52% to 75%(15), and although there is a scarcity on the reporting of media multi-tasking in children, our own preliminary data suggests that 60% of children are engaging in the practice (C.1.1). Thus far, the effects of multi-tasking on cued eating have not been examined. Given that one in three children in the United States is overweight or obese (16) and that excess weight in childhood increases the lifelong risk of many health problems (17-21), understanding why children gain excess weight and how to prevent it is essential to the NIH's mission of improving our nation's health.

Food cues activate brain reward systems that prompt cravings and eating.

Though complex neural regulatory systems monitor the body's energy stores and prompt feeding behaviors to match energy requirements (22), non-homeostatic (hedonic) mechanisms also drive consumption of highly palatable foods (23,24). The dopaminergic mesolimbic pathway is central to hedonic eating because it detects rewarding food stimuli and prompts cravings and eating (25). In addition to the sight and smell of actual food, neuroimaging studies from our group (1,25) and others (26,27) demonstrate that images of food also stimulate this pathway and that food-cue-related activity in this pathway is related to subsequent snack food consumption (28) and weight gain (25). Limiting non-homeostatic cued eating is essential for healthy weight maintenance, because even modest caloric excesses can accumulate into substantial weight gain over time (29,30).

Media multi-tasking may alter neural attentional networks and thereby increase attention to food cues and prompt greater consumption.

Attention to peripheral food cues is controlled by a series of attentional networks. The frontoparietal attentional network is responsible for filtering distracting environmental cues, and the ventral and dorsal orienting attentional networks are responsible for shifting and focusing attention to peripheral cues (3-5). Research has shown that these networks undergo a critical developmental period during childhood in which changes that occur during this period often track into adulthood (11). Frequent media multi-tasking has been associated with increased attention to peripheral cues. This result was documented by Nass and colleagues who studied how an individual's self-report of light or heavy usual media multi-tasking related to their performance on well-established behavioral paradigms of attention (8). Neuroimaging studies have shown that media multi-tasking is associated with activity in brain areas of the frontoparietal attentional network (6), and our own pilot data has shown that high media multi-taskers have greater cue reactivity to extraneous food cues in known brain reward areas (C.1.2). Consistent with these findings, high media multi-taskers are known to have a greater spread of attention to peripheral cues (7). These studies are based on a well-established attentional network theory of attention (3-5) and provide converging behavioral and neuroimaging evidence that high media multi-taskers are particularly susceptible to the influence of peripheral cues. The cross-sectional nature of these past studies limits inference about the direction of causality between media multi-tasking and attention to peripheral cues. We will address this limitation in the literature through our controlled experimental design. In addition, no studies have considered the effects of media multi-tasking on attention to food cues and consumption. The effect of media multi-tasking on attention to environmental food cues, specifically, is warranted because some evidence suggests that food cues require different attentional demands than less salient cues (31-33). There is a potentially large significance in understanding how media multi-tasking affects attention to food cues given that attention to food cues has been robustly related to consumption in both adults and children in a number of studies that have used a variety of attention paradigms (2,34,35).

Attentional training reduces attention to peripheral environmental cues.

It is possible to decrease the amount of attention given to peripheral food cues through attention modification training (36-38). Research in adults (36) and children (9) support our contention that one-session attention modification training can decrease immediate consumption. In addition, a study of a large sample of undergraduates showed that activation of executive control using the Stroop Task reduced the amount of attention given to food cues in a subsequent dot-probe paradigm, suggesting that acute manipulations of attention can have immediate effects on the amount of attention given to food cues (39). This is consistent with the robust research in the anxiety domain that has shown one-time attention modification training can reduce the amount of attention given to threating cues (40). To date, however, there have been no studies that have looked at the effect of attention modification training that improves sustained attention (AMT-S) on the amount of attention given to food cues. AMT-S may be particularly effective at reducing attention to peripheral food cues in children, because it is based on a translational neuroscience approach in which the therapeutic action directly targets the brain's attentional networks, rather than specific types of cues. For example, research with neglect patients showed that AMT-S training produced increased activation in the superior parietal cortex and right and left frontal areas and anterior cingulate cortex. These brain regions have been associated with all three attentional networks (41,42). This generalized attention training may be the most effective given the heterogeneity of food cues in our current obesogenic environment. In addition, AMT-S interventions are uniquely promising because the mechanisms associated with sustained attention are the opposite of the automatic, poorly filtered attention thought to underlie the negative effects of media multi-tasking (43). For example, sustained attention is the ability to focus and self-sustain mindful, conscious processing of task-relevant stimuli that would otherwise lead to habituation and subsequent distraction to extraneous stimuli (44). Consistent with this suggestion, a short-term intervention that has been shown to improve sustained attention in undergraduates (45) has also been shown to reduce the maladaptive attentional processing associated with media multi-tasking. The study conducted with a large sample of young adults showed that AMT-S improved performance on a battery of attention tasks - including filtering and distractibility - in both high- and low-usual media multi-taskers, but this effect was greater for high media multi-taskers (43).

2. Objectives and Hypotheses

Our long-term goal is to understand the determinants of children's individual susceptibility to environmental food cues and cued eating to develop interventions that reduce childhood obesity. Our overall objective is to determine how media multi-tasking affects attention to peripheral food cues and overeating, and whether it is possible to intervene on this proposed pathway. We have two central hypotheses. The first is that engaging in media multi-tasking increases attention to peripheral cues and thereby makes children more susceptible to environmental food cues (e.g., food advertising, sight or smell of food) that leads to cued eating in the absence of hunger. The second is that attentional training that improves sustained attention protects children against attention to peripheral food cues and therefore makes them less susceptible to cued eating.

3. Study Design

Describe all study procedures, materials, and methods of data collection:

We will achieve our aims by having 13-17-year-olds visit the laboratory on three occasions to complete each of three tasks: a media multi-tasking paradigm, an eye-tracking task that measures attention to food cues, and an EAH paradigm. Additionally, children will complete a questionnaire-based media multi-tasking scale. Children will be randomized to complete the multi-task, sustained attention, or control condition of the media multi-tasking paradigm during their first visit and will complete the alternate conditions during their second and third visits. The experimental flow for individual laboratory visits is shown in **Figure 2.**

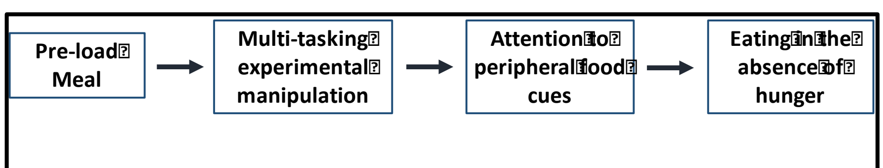

Figure 2: Experimental Flow

Participant recruitment and enrollment. We will recruit 150 children, aged 13-17-years-old using listservs, community postings and in-person recruitment in family-centered organizations such as schools, pediatric clinics, and community centers, and postings on social media platforms such as Facebook. Participants may be recruited under study-specific recruitment efforts and/or our general recruitment efforts for all the studies our lab is currently running. In addition, we will also recontact participants from a list of participants who have previously enrolled in studies in our lab. Parents of these children have consented to being contacted for future studies. We will periodically send all families in our database e-cards to thank them for their participation in our studies and also to let them know that we are recruiting participants for multiple studies. The study will be promoted as a study to investigate how children process information from different types of media; specific study goals will be concealed from children until the end of the study to prevent biasing participant behavior. However, parents of children will be told the true nature of the study prior to providing consent for their child's participation so that they can make an informed decision. We will ask the parent not to share the true purpose of the experiment until the study is over. Exclusion criteria will include inadequate English proficiency, a vision disorder that is not corrected with corrective lenses, and relevant food allergies. Exclusion criteria will be confirmed by the parent during the initial consent procedure via telephone. After initial parental consent is obtained verbally via telephone, study staff will schedule three dinnertime or lunchtime appointments and ask that children eat normal meals and snacks the day of the appointment, but refrain from eating within 45 minutes of their appointment. At the appointment, staff will obtain informed consent/assent. Following consent, children will complete the experimental flow in Figure 2.

APPROACH

Main Study

We will achieve our aims by having 13-17-year-olds visit the laboratory on three occasions to complete each of three tasks: a media multi-tasking paradigm, an eye-tracking task that measures attention to food cues, and an EAH paradigm. Additionally, children will complete a questionnaire-based media multi-tasking scale. Children will be randomized to complete the multi-task, sustained attention, or control condition of the media multi-tasking paradigm during their first visit and will complete the alternate conditions during their second and third visits. The experimental flow for individual laboratory visits is shown in Figure 2.

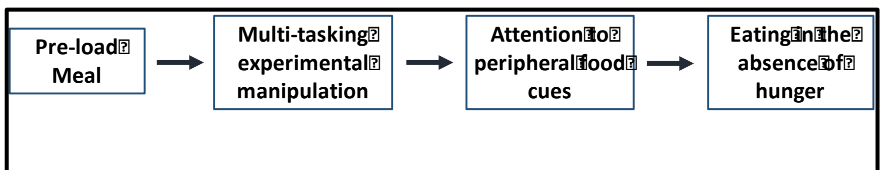

Figure 2: Experimental Flow

Preload meal. *In* order to control for satiety, children will be fed a standardized palatable dinner at the beginning of the study using established methods (48).

Multi-tasking experimental manipulation. Immediately following dinner, children will complete one of three conditions (attentional training, acute media multitask, or control) in a modified version of the Go/No-go task to simulate media-multitasking.

Attentional training. A Go/No-go task was used to train sustained attention. For the task, a blue or yellow dot briefly appeared for between 20 - 1500 msec and then disappeared. Participants were instructed to respond to the blue dot by pressing the space bar as quickly as possible (Go trials) and were told not to respond when presented with a yellow dot (No-go trials). At random intervals between 2000 – 5000 msec the messaging bot would ding and send participants a text message. The text message included questions about random facts; for example, how many teeth does an alligator have? Participants were instructed to ignore the messages and focus on the Go/No-go task. By asking participants to practice ignoring incoming messages and focus on a task designed to increase sustained attention, the training condition was designed to reduce acute media multitasking and increase sustained attention. Participants completed 100 Go trials and 100 No-go trials randomized on a trial-to-trial basis. There was a total of 60 messages sent to participants.

Acute media multitask. Participants were asked to monitor and engage with two different tasks simultaneously. On the left side of the screen, a blue dot would briefly appear and then disappear (between 20 - 1500 msec) and participants were instructed to press the space bar as quickly as possible whenever the blue dot appeared. On the right side of the screen, a messaging bot would ding and send participants a text message randomly every 2000 – 5000 msec. The questions were identical to those from the attentional training task.

Unlike the attention training condition, participants were asked to attend to and type answers to the text messages as possible. Participants were instructed to guess if they did not know the answer. Participants completed 100 trials and received a total of 60 messages.

Control condition. For the control condition, participants were asked to passively watch a video simulation of the media multitask condition with no specific instructions of where to look.

Attention to peripheral cues. Immediately following the multi-tasking experimental manipulation, children will play a game of Tetris that measures attention to peripheral cues using eye-tracking. On either side of the game screen are pictures of food and animals that change periodically. Study staff will set up children with the task, provide directions, have children do a practice trial game, and clarify directions if necessary. The food cue is chosen at random on a game-to-game basis. To encourage gameplay concentration, children are encouraged to complete as many games as possible within 10 minutess. This game has high ecological validity because it mimics Internet advergames that are used to advertise products to children (2). We will use established eye-tracking metrics to measure attention to food cues. The amount of attention given to peripheral cues while playing the video game Tetris will be calculated for each participant after they completed each experimental condition. Areas of interest will be created around distractor images, defined as the area of the image, 250 X 250 pixels. First fixation duration will be measured as the average amount of time an adolescent spent fixating a distractor the first time that they looked at it. Cumulative fixation duration will be calculated as the total amount of time participants spent fixating distractors, summed over all fixations. For both measures, a fixation duration will be defined as any stationary period lasting at least 100 milliseconds. Eye-tracking will be recorded using the EyeLink 1000 Plus (SR Research, Ottawa, Ontario, Canada). The EyeLink is a robust desktop configuration that also includes facial recognition software to monitor head movements. This ability to compensate for head movements is particularly useful because it assures that when participants look away from the stimulus and then return to it, the system will automatically reacquire the eye. Critically, the video used to track the eyes is not saved and the person's likeness is never recorded.

Eating in the absence of hunger (EAH) measurement. When the child finishes the memory game, he/she will be asked to "wait in the room" for 10 minutes while the experimenter allegedly takes care of tasks in a different room. During this period, the waiting room will contain pre-weighed snack items and games to measure EAH using established methods (1,58). The pre- and post-weights of each snack item will be used to calculate the number of kCal the child consumed. The EAH phase will take place within 20 minutes of the standardized dinner.

Assessing usual media multi-tasking. Children will complete the media multi-tasking index (MMI) (8). This index asks about media multitasking with other print and digital media during four primary activities: 1) watching TV or movies, 2) playing video games, 3) reading books or magazines (not assigned for school), and 4) doing homework. For each activity, participants reported the frequency with which they multitasked by engaging in the other activities by using a 5-point likert scale (i.e., 0=*Never*, 1=*Rarely, 2=Sometimes, 3=Often, 4=Always*). A usual media multitasking score was computed by taking the average of the Likert response. The score ranges from 0 to 4 with a higher score indicative of higher self-reported usual media multitasking. on cognitive control tasks (8,59,60).

Potential covariates. We will assess potential covariates for potential inclusion in analyses for Aims 1-3. Given the association between exercise and increased attentional processing in preadolescent children (61), we will assess usual **physical activity** using the ActiGraph GT3X-BT triaxial accelerometer (ActiGraph LLC, Pensacola, FL) for 7 days between the first and second visit using established methods (62-64). Relatedly, it is important to record physical activity to isolate the effect of media multi-tasking on cued eating, from the effect of general sedentary behavior that media multi-tasking is potentially a proxy. Children will also be asked to self-assess their **pubertal maturation** using the Pubertal Development Scale, which has shown strong validity and acceptability in our age group (65-67). Before administering this scale, the experimenter will emphasize that responses are voluntary, and that if the child simply does not understand some questions, his/her parent will offer responses. We will have children report on their **media exposure** using a questionnaire adapted from the Kaiser Foundation (14), and their **health knowledge and attitudes about the provided food** (68)**.** Parents will report on their child's **sleep duration** using the Adolescent Sleepiness Scale, the Adolescent Sleep-Wake Scale, and the Adolescent Sleep Hygiene Scale (69), eating behaviors using the child eating behavior questionnaire (CEBQ) (71), and **sociodemographic variables** (i.e., education, household income, race, and ethnicity). **Height and weight** will be measured using standard methods (72) to calculate age- and sex-specific **BMI z-scores** (73). These variables will be collected via a parent questionnaire that will be completed by the parents via an online questionnaire sent securely through RedCap.

4. Analysis

Describe any qualitative tests and measures as well as quantitative methods:

Our primary outcomes of interest will be ∆first fixation duration to peripheral cues, ∆ cumulative fixation to peripheral cues, and ∆EAH and our primary exposures will be the multi-task vs. control condition and the sustained attention task vs. control. We will first assess main effects of the acute tasks by using multivariable linear regression to fit ∆ attention eye-tracking metrics on ∆EAH. Cohen's power calculation for regression, and setting alpha to $P < .05$, two-tailed, we calculated 80% power to detect a moderate effect size ($f^2 = .15$) for main effects. To test for moderation, we will then repeat the main effects models stratifying the sample by the median of usual media multi-tasking. We will conduct a formal test for interaction by repeating the main effects models on the entire sample with the acute task, usual media multi-tasking, and the product of the acute task and usual media multi-tasking as the independent variables of interest. A Wald test on the product term $P < 0.10$ will be considered evidence of a statistically significant interaction.

To examine the effects related specifically to food images, we will repeat all analyses using first fixation bias and cumulative fixation bias to food cues as our outcomes of interest. A first fixation bias to food cues was calculated by computing the difference between first fixation duration to food and animal images. A positive value represents that a child looked longer the first time they fixated a food versus toy distractor. A cumulative gaze duration bias to food cues was calculated by computing difference between cumulative fixation duration to food versus toy animal distractors. A positive number indicates that a child spent more total time looking at food versus toy distractors.

We assessed power to detect a significant correlation between each predictor and our outcome using Cohen's method for Pearson's correlation coefficient (74). Using 107 participants (assuming a retention rate of 85%), 80% power, and a Type I error rate of 0.05 (two-tailed), we calculated that Aim 1 is powered to detect a moderate effect size of $|r \geq 0.27|$ for either predictor with EAH. Cross referencing this effect size and our power analysis parameters with the empirical power tables for mediation created by Fritz and Mackinnon (75), we found that that our study is 80% powered to detect if media multi-tasking fully mediates the relationship between attention to food cues and EAH.

5. Study Progress Monitoring

Note: appropriate monitoring may include periodic assessment of the following:

- data quality
- timelines
- recruitment and enrollment

Provide a description of the methods which will be used to determine the progress of the study, including periodic assessments of data quality, timelines, recruitment, and enrollment as appropriate:

Data collected via web-based electronic data collection forms will include internal logic and quality control checks to ensure data is valid at the point of entry. Data errors will need to be updated by the participant before data will be saved. A data analyst will assess all data collected for quality and face validity; data that is perceived to be inaccurate may be excluded from analyses. Our team will create a study timeline at the start of any participant recruitment, and we will review the study's progress including adhering to the timeline biweekly.

Team meetings will assess recruitment, enrollment and study completion rates. A log of those rates will be kept in real time. Research staff will report to the PI any concerns with the study administration.

6. Risks & Benefits

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

a. Describe any potential risks, their likelihood and seriousness:

1. Exposure to Food Allergens: The children will be consuming a standardized meal as well as snack foods. Children with food allergies could experience an allergic reaction to food ingredients

2. Loss of confidentiality: We will collect behavioral and socio-demographic information. Loss of privacy may lead to problems with insurability or social stigmatization

b. Confirm that risks to subjects have been minimized, by use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:

1. Exposure to Food Allergens: We will request information about the child's food allergy status multiple times. We will ask the parent if the child has any food allergies during the initial recruitment telephone call and in the written consent form. We will additionally ask both the parent and child whether the child has any food allergies before the child begins his/her participation in the study. Children with relevant food allergies will be excluded from this study to avoid the possibility of an adverse allergic response.

2. Confidentiality: Data collection and analysis will be handled in a confidential manner to protect subject privacy. All electronic data will be stored in a password-protected and encrypted database on a secure Dartmouth server. All paper files will be stored in a locked file cabinet in a secure office. All subject data will be de-identified, and only the primary investigator and research team members who directly contact the participants will have access to the information necessary to link them to their de-identified data. The information collected for this study will be used only for purposes of the research as stated earlier in this form and data will be destroyed when it is no longer needed.

c. Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:

This study involves minimum risk to participant, and the study findings are to benefit the broader population. Any risks to participants associated with the study are thought to be reasonable.

7. Unexpected Events or Incidental Findings

Note: It may be important to consider the potential for certain unanticipated events to occur, for example:

- finding an anomaly in a MRI
- discovering child abuse
- causing distress in interviews of a sensitive nature

Describe potential events and provide a plan of action:

We do not anticipate any adverse effects. Should any children or parent experience discomfort during the study, he/she will be encouraged to contact the PIs, Dr. Diane Gilbert-Diamond at (603) 653-3362, or the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-3053. If any participant expresses a desire to learn more about health behaviors for their child, the participant will be directed to relevant material published by the U.S. Centers for Disease Control and Prevention or the USDA.

8. Deception

Does any part of this study involve deception or withholding of information from participants?

☒ **Yes** ☐ **No**

If Yes, provide an explanation which addresses the following:

- A description of the deception being used
- Why the deception is necessary
- A plan for debriefing, or providing subjects with the pertinent information after participation

We will not completely disclose the purpose of the main study or the purpose of the sub-study to participants in order to avoid bias. This may lead to the participants feeling distressed about being deceived or distrustful of scientific research. In order to address the risks associated with not completely disclosing the research aims of the study, we will send a letter to parents that explains the full purpose of the study when the study is complete. We will explain that we did not reveal the study purpose because we thought that such knowledge might have influenced their children's behavior. We will provide our contact information so that parents and/or their children can discuss the study further if they desire. These procedures will also be followed for the sub-study.

The full debriefing of the main study reveals the objective of the Tetris game, which is to assess how much attention participants pay to the peripheral food cues as they play Tetris. However, because the Tetris game is used for the same purpose in the sub-study, fully debriefing participants after they finish the main study but before they complete the sub-study (as is our current protocol) may affect their responses in the Tetris game during the sub-study. For this reason, those participants in the main study that choose to participate in the sub-study will be debriefed of both studies after they complete the sub-study.

9. Equitable Participant Selection

a. Estimated number of participants at Dartmouth CPHS reviewed sites:

150 child-parent dyads.

b. Provide a justification of the proposed sample size

For the main study, we consider a sample size of 120 to have enough statistical power in this study. It is possible that we recruit up to 150 child-parent dyads, in the event that we deem necessary to modify study procedures or add new measurements.

c. Define the target population:

Adolescents, aged 13-17 years.

d. Vulnerable populations

<u>Note:</u> Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the 'Supporting Documents' page in Rapport.

☐Pregnant Women, Fetuses and Neonates

☒Children

☐People with impaired decision-making capacity

The following populations may also be considered vulnerable to coercion or other undue influence:

- Prisoners
- People who are economically disadvantaged
- The elderly
- People who are illiterate or do not speak English
- Students and employees

Describe any other potentially vulnerable population(s) and the additional protections provided to them:

N/A

10. Recruitment

Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport.

We will recruit 150 children, aged 13-17-years-old using listservs, community postings and in-person recruitment in family-centered organizations such as schools, pediatric clinics, and community centers, and postings on social media platforms such as Facebook. In addition, we will also recontact participants from a list of participants who have previously enrolled in studies in our lab. Parents of these children have consented to being contacted for future studies. We will periodically send all families in our database e-cards to thank them for their participation in our studies and also to let them know that we are recruiting participants for multiple studies.We will target our recruitment to communities of lower to middle socioeconomic status by recruiting from communities with higher rates of eligibility for free/reduced meals in the National School Lunch Program within the town's public elementary schools; those data are publicly available via state-level departments of education. By expanding our recruitment catchment area and adding additional staff time to recruitment, we are confident that we can reach our enrollment target within the study period. Participants for the sub-study will be recruited from the group of participants who successfully complete the main study and who express interest.

11. Informed Consent, Assent, and Authorization

All forms discussed in this section should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport

a. **Please describe the consent and/or assent process, addressing the following:**
   - Who will obtain consent/assent from participants
   - Where the consent/assent process will take place
   - The timeframe for providing information potential participants about a study, having the consent form signed, and beginning study activities
   - Any precautions taken to minimize the possibility of coercion or undue influence

- The forms which will be used as well as any aids used to simplify scientific or technical information
- How comprehension will be ensured

When a parent first contacts the study to express interest in having his/her child participate in the study, a thorough screening interview will be conducted over the phone, at which time the study procedure will be described in detail (including financial compensation). When the child (and parent) visit the lab for their study appointment, trained research staff will explain the study in plain language and obtain electronic written consent from the parent and electronic written assent from the child, both via REDCap. The study will be promoted to the child as a study to understand how exposure to multi-media types influences children; specific study goals will be concealed to prevent biasing participant behavior. It will be emphasized that the child can choose to stop participating in the study at any time. Parents of children will be told the true nature of the study prior to providing consent for their child's participation so that they can make an informed decision.

b. Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk.
Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the Waivers and Alterations Request Form and upload it to the 'Consent Forms and Recruitment Materials' page in Rapport.

☐ For the informed consent *process*
☐ For the *documentation* of informed consent
☐ For the HIPAA Authorization to use and/or disclose PHI
☐ For a waiver of the requirement for medical record documentation

12. Compensation or Gifts

Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:

For the main study, parent/child dyads will receive increasing compensation for each visit. Specifically, participants will receive $30 for attending the first appointment, $40 for the second visit, and $70 for attending the third visit. Participants will also be compensated $10 for each visit when they are driving more than 15 miles to participate. In addition, participants will receive $20 for participating in wrist-worn accelerometry between visits 1 and 2. Parents of participants will be compensated $10 for completing a short online questionnaire. Participants may be compensated in the form of cash or gift cards.

13. Privacy of Participants

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

- Consent discussions or interviews held in public which concern sensitive subjects or behaviors
- Observations of behavior, especially illicit behavior, in quasi-public settings

Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:

We will collect behavioral and socio-demographic information. Loss of privacy may lead to problems with insurability or social stigmatization. Data collection and analysis will be handled in a confidential manner to protect subject privacy. All electronic data will be stored in a password-protected and encrypted database on a secure Dartmouth server. All paper files will be stored in a locked file cabinet in a secure office. All subject data will be de-identified, and only the primary investigator and research team members who directly contact the participants will have access to the information necessary to link them to their de-identified data. The information collected for this study will be used only for purposes of the research as stated earlier in this form and data will be destroyed when it is no longer needed.

14. Confidentiality of Data

Note: Any person engaged in research collecting information that could cause financial, social or legal harm to participants may apply for a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They are intended to allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

a. If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?

☒ **No** ☐ **Yes**

If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:

b. Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:

- Administrative, ie. coding of participant data
- Physical, ie. use of locked file cabinets
- Technical, ie. encrypted data systems

Data collection and analysis will be handled in a confidential manner to protect participant privacy. After enrolment in the study, each participant will be assigned a participant identification number that will be used, rather than their names, to track data collection. All participant data will be deidentified, and only the primary investigator and research team members who directly contact the participants will have access to the information necessary to link them to their de-identified data. All electronic data will be stored in a password-protected and encrypted database on a secure Dartmouth server. All paper files will be stored in a locked file cabinet in a secure office. The information collected for this study will be used only for purposes of the research.

c. Describe the plan for storage or destruction of data upon study completion:

All information and for the purpose of this research will be destroyed when it is no longer needed.

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