# University of Kansas Medical Center
# RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS
# TEMPLATE WITH GUIDANCE

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**Study Title:** Developmental Decision Making Study

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## I. Purpose, Background and Rationale

### A. Aim and Hypotheses

1. The proposed research will investigate food decision-making in youth. Childhood obesity is a risk factor for health issues, thus preventing adverse effects of childhood obesity by promoting healthy eating habits and providing effective interventions are important. Television food commercials advertising calorie-dense and high in salt and sugar foods are known to contribute unhealthy food choices and obesity. Thus the proposed study will examine how the advertising intervention focusing on increasing advertising knowledge and changing affective attitudes toward commercials impacts susceptability to commercials and food decisions in youth.
2. The objective of this proposed study is to examine the advertising intervention's effect on susceptibility to food commercials and food decision-making in children ages 8 to 12. Interventions will be narratives to increase cognitive defenses including advertising knowledge and skepticism (e.g., "the commercials aren't telling the truth"), and change affective responses toward commercials (e.g., "These foods don't make you happy"). Susceptibility to commercials will be measured by preference and desire for the advertised foods. Only children in intervention group will have four sessions for watching food commercials accompanied by intervention during a week. Children in control group will have four sessions for watching food commercials, however, no intervention will be accompanied. This project will accomplish the following: Aim 1. Assess the impact of the food advertising interventions on susceptibility to food commercials in children. We hypothesize that the advertising intervention will increase cognitive defenses and negative attitudes toward advertised foods in the intervention group. And intervention effects will decrease likeness and desire for advertised foods in the intervention compared to control group. Aim 2. Examine how the food advertising intervention impacts behavioral food decisions. We hypothesize that children in the intervention group will demonstrate healthier food choices. Aim 3. Examine how the self-control ability influences the food intervention effect and behavioral food decisions. We hypothesize that higher self-control ability will predict a more successful intervention effect and healthier food choices in youth.

### B. Background and Significance

1. Study Significance: This study will be the first investigation of food advertising interventions on susceptibility to food commercials and behavioral food decisions in children. It will also enhance our knowledge of how children's self-control is involved in promoting healthier food choices.

2. One third of children and adolescents are overweight or obese in the U. S., and this high prevalance of childhood obesity has been remained the same throughout the past decade (Ogden, Carroll, Kits, & Flegal, 2014). Examining factors impacting childhood obesity and finding effective prevention and intervention approaches are crucial for reducing the childfood obesity epidemic. Television food commercials advertising non-nutritious foods are known to be one of the factors to impact child obesity. The proposed study will investigate how the advertising intervention influences susceptibility to food commercials and food choices in children. Also this study will examine how children's self-control ability impact the intervention effect and food decision-making.
3. Literature Review: Childhood obesity is a risk factor for health issues such as cardiovascular disease and diabetes, and for psychological issues such as low self-esteem and negative body image (Must & Strauss, 1999). One third of children and adolescents are overweight or obese in the U.S. (Ogden, Carroll, Kit, & Flegal, 2014). These overweight or obese children are at increased risk of becoming obese adults (Serdula, Ivery, Coates, Freedman, Williamson, & Byers, 1993). To prevent immediate and long-term adverse effects of obesity, providing effective childhood obesity interventions is important. Television food commercials are known to be one of factors that impact child obesity. Many television food commercials advertise calorie-dense and high in salt and sugar foods, so that frequent exposure to them contributes unhealthy food choices and obesity (Harris, Bargh, & Brownell, 2009). Obese children are more likely to be susceptible to priming of food advertising, which results in increased consumption of brand name and unhealthy foods (Boyland & Halford, 2013; Forman, Halford, Summe, MacDougall, & Keller, 2009). Neuroimaging findings also suggest that obese children's brains respond differently than healthy weight children to food advertising (Bruce et al., 2013). It is only recently that advertising interventions have been developed to decrease advertising effects in children. Buijzen (2007) developed advertising interventions consisting of a factual intervention building cognitive defenses including advertising knowledge (i.e., knowledge of persuasive intent of commercials) and advertising skepticism (i.e., doubt the truth of commercials). They also developed an evaluative intervention to change affective responses toward commercials. Children showed reduced advertising susceptibility (i.e., intended product requests) after they received advertising interventions on toy commercials. The proposed study will apply the advertising intervention to food commercials. Moreover, the proposed study will examine the of self-control ability in the advertising intervention effect and behavioral food decision-making. Neuroimaging findings suggested that obese children were more susceptible to external food cues such as fast food advertising, and brain activations in cognitive and self-control regions were greater in healthy weight children than in obese children (Bruce et al., 2013). Children's self-reported inefficiency in executive functioning predicted greater unhealthy food choices (Riggs, Spruijt-Metz, Sakuma, Chou, & Pentz, 2010). And normal weight children with high self-control showed less weight gain during the transition from preadolescence to adolescence (Duckworth, Tsukayama, & Geier, 2010). In pediatric obesity research, the ability to execute inhibitory control assessed by behavioral measures was less efficient in overweight and obese children compared to normal weight children (Reyes, Peirano, Peigneux, Lozoff, & Algarin, 2015). And less effective inhibitory control was related to unsuccessful weight loss among obese children (Bruce, Martin, & Savage, 2011; Nederkoorn, Braet, Van Eijs, Tanghe, & Jansen, 2006; Nederkoorn, Jansen, Mulkens, & Jansen, 2007).

### C. Rationale

1. Buijen (2007)'s findings suggest that the advertising intervention is effective to change susceptibilities to the commercials, thus we expect the food advertising intervention would impact children's susceptibilities to food commercials. Research findings suggest that obese children's high susceptibility to food commercials leads to unhealthier food choices. Thus, we expect the reduced susceptibility to food commercials after the intervention would be resulted in changes in food choices. Based on findings that inefficient self-control involves in greater unhealthy choices and poorer weight control in both healthy weight and obese children, we expect the self-control ability would mediate the advertising intervention effect and behavioral food choices.
2. The proposed project will advance our understanding of how changes in cognition (advertising knowledge) and affection (attitudes toward commercials) impact children's preference and desire for the advertised foods, and how this intervention effect influences children's healthier food choices. Also this study will examine how children's self-control ability influence the intervention effect and food choice process. Based on hypothesized findings, we would have better understanding of how food advertising influences overweight or obese children's susceptibility to the advertised foods and in-general food choice patterns.
3. If the advertising intervention was effective, we could apply the advertising intervention to the treatment of overweight and obese children to reduce susceptibility to food commercials and to enhance healthier food choices. Also if children's self-control ability played a role in the intervention effect and food decision-making, we could develop the intervention focusing on enhancing self-control skills in children with obesity.

## II. Research Plan and Design

**A. Study Objectives:** This study will investigate how food advertising interventions impact susceptibility to food commercials and behavioral food decisions in children. This study will also examine the role of self-control in food advertising intervention effects and behavioral food decisions. Aim 1. Assess the impact of the food advertising interventions on susceptibility to food commercials in children. Aim 2. Examine how the food advertising intervention impacts behavioral food decisions. Aim 3. Examine how the self-control ability influences the food intervention effect and behavioral food decisions.

**B. Study Type and Design:** This study will be a pre-test and post-test control group study. Children will be randomly assigned to either the intervention or the control group. Children in the intervention group will have four sessions for watching food commercials accompanied by interventions during one week, and children in the control group will have four control sessions only watching food commercials. To assess the impact of the food advertising interventions, children will be asked to rate susceptibility to food commercials, i.e., their desire and preference for the advertised foods. To examine how the food advertising intervention impacts behavioral food decisions, children will be asked to rate various food items (e.g., apple, donut) for food related attributes (e.g., health, taste). Also children will make yes/no choices on various food items to determine whether children want to eat the presented food items. To examine if exposure to food cues increases food consumption in child, they will be given the opportunity to consume snack foods after viewing the commercial video clips. To examine how the self-control ability involves in the food intervention effect and food decision-making, children's self-control ability will be measured by behavioral tasks and self-report questionnaires.

**C. Sample size, statistical methods, and power calculation**

1. Children will be randomly assigned to the intervention and the control groups, and the randomization ratio between the intervention and the control groups will be 1:1. The statistical methods will be using an Analysis of Variance (ANOVA) and a correlation analysis. All analyses will be conducted at the alpha level of .05 ($p < .05$).
2. N/A
3. The proposed study will recurit approximately 60 subjects. Regarding the aims 1 and 2, G*Power's a priori power analysis for an ANOVA test indicate that 80% power with an effect size of .25 (medium effect) can be achieved from the total of 24 subjects (12 subjects in each group). Regarding the aim 3, G*Power's a priori power analysis for a correlation indicted that 80% power with an effect size of .25 (large effect) can be achieved from the total of 29 subjects (15 subjects in each group).

**D. Subject Criteria (See Vulnerable Populations appendix, if applicable):** Healthy children ages 8 to 12 who speak English as the primary languge will be included.

1. Inclusion criteria: Children and preadolescence between ages 8 and 12 who speak English as their primary language will be included. All participants will have self-reported normal hearing and vision.
2. Exclusion criteria: Data from children with history of neurological conditions, clinically significant psychopathology or learning disabilities reported by parents (e.g., ADHD, depression) will be excluded. Due to the food commercials and intervention narratives are spoken in English, non-English speakers will be excluded.

3. Withdrawal/Termination criteria: Unless a subject wanting to withdraw from participation, it is not expected that the investigators to determine a participation termination.
4. Subjects may not participate in another research study.

**E. Specific methods and techniques used throughout the study**

1. Laboratory tests: No laboratory tests will be collected. Children's height and weight will be measured to calculate the body mass index (BMI).
2. Study Procedures: Upon arrival, parents and children will be asked to read and sign an informed consent form. The experimenter will explain the study and answer any questions at that time. Children will be randomly assigned to the intervention and control groups, and they will have the total of four sessions during a week period. The session will be expected to be completed for two to two and a half hours. Half of the sessions will take place at the laboratory and the rest half will take place at home. Children in the intervention group will watch familiar fast-food commercials (e.g., McDonald's) accompanied by factual (e.g., "These commercials are't telling the truth.") and evaluative interventeion narratives (e.g., "These foods don't make you happy."). Children in the intervention group will be encouraged to speak aloud their current thoughts while watching commercials to boost their information processing. Children in the control group will watch familiar fast-food commercials, however, no intervention will be followed. Children will complete self-report questionnaires related to eating behaviors, susceptibility to commercials, and other psychological characteristics. Behavioral tasks will be administered to children including food attributes ratings (e.g., health, taste), food choice tasks, food brand logos ratings (e.g., health, taste), mousetracker food choice tasks (i.e., measuring real-time food choice process by tracking mouse trajectories during yes/no choices), and self-control tasks.
3. All procedures described in the section E2 will be performed solely for research purposes.
4. N/A
5. Timeline: Participants will have four sessions during a week period, and they will complete self-report questionnaires and behavioral tasks before or after a session.

**F. Risk/benefit assessment:**

1. Physical risk no known risks
2. Psychological risk no known risks except for inconvenience of time spent completing the study
3. Social risk no known risks
4. Economic risk no known risks
5. Potential benefit of participating in the study
    a. It may not be direct benefits, but participation in this study would allow participated children and parents to gain a better understanding of the influence of food commercials and healthy food choices.
    b. Children and parents will gain a better understanding of the influence of food commercials and healthy food choices.
    c. Findings from this proposed study will allow researchers to gain a better understanding of food decision-making in youth.

**G. Location where study will be performed:** The study will take place at KUMC rainbow campus, Children's Mercy hospital and UMKC Volker campus. The research subjects records will be kept at the KUMC research laboratory.

**H. Collaboration (with another institution, if applicable**

**I. Single IRB Review for a Multi-site study (if applicable):**

1. For which sites will KUMC serve as the IRB of record? UMKC
2. Indicate which study activities will occur at each site. If all study procedures will be identical across study sites, state this. All study procedures will be identical across study sites.
3. Describe how you will assess the capacity of each site to perform the research (e.g., expertise, staffing, space, equipment, etc.) If applicable, include site evaluation tools in your IRB submission. Dr. Oh-Ryeong Ha, Co-I, is an assistant professor in Department of Psychology at UMKC and has expertise in developmental studies. Her research laboratory space will be used for recruitment, enrollment, and testing, and the lab has computers for testing. Her research assistants will assist study activities.
4. Describe how the lead investigators will ensure that all participating sites use the IRB-approved version of the protocol, consent, recruitment materials and other study documents. Lead investigators will have training meetings to ensure all sites use the IRB-approved protocol, consent, recruitment materials and other study documents. Also it will be assessed and discussed during regularly-scheduled meetings.
5. Describe how the lead investigators will communicate with and disseminate new information to other sites (e.g., training meetings, regularly-scheduled conference calls, notifications, etc.) Lead investigators and research staffs will have regularly-scheduled meetings and any new information will be communicated promptly via email or call.
6. Describe how the lead investigator will assess protocol compliance, unanticipated problems and adverse events at other sites. Lead investigators will assess and discuss protocol compliance with research staffs at regularly-scheduled meetings, and any urgent issues will be discussed promptly among lead investigators.
7. Name the member of the KUMC study team who will be the point of contact to coordinate oversight and communication with the sites. Dr. Amanda Bruce will be the point of contact for communication with the sites.

**J. Community-Based Participatory Research (if applicable)**

1. Participants and the nature of their involvement:

2. Cultural issues

3. Origin of the research question:

4. Risks and Benefits:

5. Study Description and Process:

6. Return of results:

7. Sustainability:

**K. Personnel who will conduct the study, including:**

1. Indicate, by title, who will be present during study procedure(s): PI, Co-I, and research personnel
2. Primary responsibility for the following activities, for example:
    a. Determining eligibility: PI, Co-I, and research personnel
    b. Obtaining informed consent: PI, Co-I, and research personnel
    c. Providing on-going information to the study sponsor and the IRB: PI, Co-I, and research personnel
    d. Maintaining participant's research records: PI, Co-I, and research personnel
    e. Completing physical examination: PI, Co-I, and research personnel
    f. Taking vital signs, height, weight: PI, Co-I, and research personnel
    g. Drawing / collecting laboratory specimens:
    h. Performing / conducting tests, procedures, interventions, questionnaires: PI, Co-I, and research personnel
    i. Completing study data forms: PI, Co-I, and research personnel
    j. Managing study database: PI, Co-I, and research personnel

**L. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan**

1. Elements of the plan include:
    a. Persons/groups who will review the data (study team; independent safety monitor, data monitoring committee or formal DSMB)
    b. Data/events that will be reviewed
    c. Frequency of review
    d. Types of analyses to be performed
    e. Safety-related triggers that would cause the PI to stop or alter the study
2.
3.

## III. Subject Participation

**A. Recruitment**:

1. Participants will be recruited from the KU Med's Pediatric Outpatient Clinic and affiliated Prairie Village Clinic (with flyers), Center for Children's Healthy Lifestyles & Nutrition, and Children's Mercy Hospital, University of Missouri - Kansas City, community facilities such as local schools, libraries, churches, and community centers around Kansas City metropolitan area.
2. Flyers will be posted at and/or emailed to the outpatient pediatric clinic at KUMC and affiliated Prairie Village Clinic, the Healthy Hawks obesity program, Center for Children's Healthy Lifestyles & Nutrition, Children's Mercy Hospital, and University of Missouri -

Kansas City such as Psych pool, i.e., Department of Psychology online research participant recruitment system. And social media such as Craigslist, Facebook, television, radio, and newspapers, and word-of-mouth recruitment will be used. Individuals who express interest in the study (by email or in person) can be approached/contacted by the research staff. They will be explained that it is a voluntary participation and they are able to discontinue participation at any time. The study may be explained briefly in the waiting area in person. If potential participant expresses interest, the remainder of the interaction will take place in a private room at KUMC rainbow campus, Center for Children's Healthy Lifestyles and Nutrition in Children's Mercy Hospital, and UMKC Volker campus.

3. The email advertisement will be worded as follows:

Researchers at the University of Kansas Medical Center and the University of Missouri - Kansas City are conducting a study investigating food commercials and food choices. The study will require two 2-2.5 hour visits and two 15-minute home sessions. Parental consent and involvement is required.

To qualify, you must:
Be between the ages of 8 and 12
Speak English as your primary language

The participant will be compensated with $50 for participation in the study. Email today to be part of a research study: Bruce.Neuro@gmail.com or call 816-235-6494.

4. Potential participants will also be contacted via letters to parents or phone calls. They will be told that study participation is voluntary and they are able to discontinue at any time. The contact list will be compiled through the Frontiers Registry at KUMC using patient names who said they would be willing to be contacted for future research opportunities. Letter to parents and phone script are attached.

**B. Screening Interview/questionnaire**: N/A

**C. Informed consent process and timing of obtaining of consent**

1 The research personnel at KUMC, at Center for Children's Healthy Lifestyles and Nutrition in Children's Mercy Hospital, or at UMKC will give detailed information about the study and obtain their written consent, and also answer questions at that time.

2 Informed consent will be obtained before any study related procedures are performed on the first day of participation. It will be obtained by one of the study investigators at KUMC, at Center for Children's Healthy Lifestyles and Nutrition in Children's Mercy Hospital, or at UMKC through signed, written consent. The consent interview will be conducted in a private room within the testing location. The door will be closed during this interview to provide privacy. The consent form will be explained fully to the participant and parent, and all of the participant and parent's questions will be answered before the form is signed. The child will provide written and verbal assent. The participant will be informed that it is a voluntarily participation thus he or she can quit the study at any time.

3 Written informed consent will be obtained from a parent or a legal guardian and written assent will be obtained from the child prior to beginning assessment. If children are able to understand, remember, and verbalize the main aspects of the study, it will be

assumed that they have the capacity to consent by a research personnel who will informe the consent.

**D. Alternatives to Participation:** Participants may choose not to participate in this study or to end participation in this study at any time. If a participant chooses to quit this study it will not affect his or her medical care or your relationship with KU Medical Center in any way.

**E. Costs to Subjects:** No clinical care will be required.

**F. How new information will be conveyed to the study subject and how it will be documented:** A research staff will explain any new information to a participant and parent, and a written consent will be obtained.

**G. Payment, including a prorated plan for payment:** Each participated child will be compensated with $20.00 after the first visit, and with $30.00 after the second visit. Travel costs will not be reimbursed.

**H. Payment for a research-related injury:** No known risks for physical injury are expected.

## IV. Data Collection and Protection

**A. Data Management and Security:**

1. PI, Co-I, and research staff member will have access to study data.
2. Identifying information will not be associated with the data collected. Each participant will be assigned a participant number. The only identifying information collected will be social security numbers for subject payment and signed informed consent forms. This information will be stored in a locked cabinet inside a locked office at KUMC. Once payment has been issued, the social security numbers will be destroyed.
3. Subjects will be indentifiable through coded information.
4. PI, Co-I, and research staff member will have access to the key to the code.
5. The data will be linked to subjects' assigned participant number.
6. The electronic study data will be housed at KUMC-supported network drive and University-owned laptops with password protection. Participants' information will be stored in a locked cabinet inside a locked office at KUMC.
7. University-owned laptop will be used and data will be stored at KUMC-supported network drive.
8. Only data associated with a participant number will be sent out with security protection.

**B. Sample / Specimen Collection:** N/A

**C. Tissue Banking Considerations:** N/A

**D. Procedures to protect subject confidentiality**: No known risks for subject confidentiality.

**E. Quality Assurance / Monitoring**

1. The research staff will explain the directions and answer questions before beginning of any study-related performances to make sure children understand the directions accurately.
2. N/A

## V. Data Analysis and Reporting

**A. Statistical and Data Analysis:** An Analysis of Variance (ANOVA) and correlation methods will be used for data analysis.

**B. Outcome**: It is expected that children in the intervention group and in the control group would show differences in susceptibility to food commercials and behavioral food choices. All analyses will be conducted at the alpha level of .05 ($p < .05$).

**C. Study results to participants**: Study results would be given to subjects after data collection is completed and the findings are published on a peer-reviewed journal by participants' requests.

**D. Publication Plan**: Research results will be planned to be published on a peer-reviewed journal.

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## APPENDIX I: VULNERABLE POPULATIONS

**I.** See below (I-III)

**II. Cognitively or decisionally impaired individuals**:

**III. Children**: Informed consent will be obtained before any study related procedures are performed on the first day of participation. It will be obtained by one of the study investigators at KUMC, at Children's Mercy Hospital, or at UMKC through signed, written consent. The consent interview will be conducted in a private room within the testing location. The door will be closed during this interview to provide privacy. The consent form will be explained fully to the participant and parent, and all of the participant and parent's questions will be answered before the form is signed. The child will provide written and verbal assent. The participant will be informed that it is a voluntarily participation thus he or she can quit the study at any time. Written informed consent will be obtained from a parent or a legal guardian and written assent will be obtained from the child prior to beginning assessment. If children are able to understand, remember, and verbalize the main aspects of the study, it will be assumed that they have the capacity to consent by a research personnel who will informe the consent. Regarding recruiments, flyers will be posted at and/or emailed to the outpatient pediatric clinic at KUMC and affiliated Prairie Village Clinic, the Healthy Hawks obesity program, Center for Children's Healthy Lifestyles & Nutrition, Children's Mercy Hospital, UMKC, and local community facilities. And social media such as Craigslist, Facebook, television, radio, and newspaper, and word-of-mouth recruitment will be used. Individuals who express interest in the study (by email or in person) can be approached/contacted by the research staff. They will be explained that it is a voluntary participation and they are able to discontinue participation at any time. The study may be explained briefly in the waiting area in person. If potential participant expresses interest, the remainder of the interaction will take place in a private room at KUMC rainbow campus, the Center for Children's Healthy Lifestyles & Nutrition in Children's Mercy Hospital, or UMKC.

**IV. Pregnant women:**

**V. Prisoners:**

**VI. Students and/or Employees:**

**A.**

**B.**

**C.**