Official Title:
Using In-depth Interviews to Examine Neighborhood Influence on Parenting Practices Regarding Youth Outdoor Play and Physical Activity

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Protocol Title: Using In-depth Interviews to Examine Neighborhood Influence on Parenting Practices Regarding Youth Outdoor Play and Physical Activity.

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Objectives

A. Specific Aims

Parental constraint of outdoor play may be fueling unhealthy emotional and physical development in today's children and adolescents. Time spent outdoors is a key determinant of unstructured play and overall physical activity levels, both of which are crucial to optimal development in youth. Modern barriers – such as crime, poor social ties among neighbors, and unsafe physical environments – constrain parental practices and reduce opportunities for outdoor play in children and youth. Low levels of perceived collective efficacy, a measure of perceived neighborhood cohesion and the collective capacity to solve neighborhood problems, has been proposed as a social environmental factor that constrains outdoor play by parents either attempting to avoid potentially dangerous situations or using defensive behavior by upgrading security measures. Moreover, incivilities in the neighborhood physical environment (e.g. litter, graffiti, blighted property) may influence parents' perceived collective efficacy. Consequently, a child's ability to achieve the recommended minimum of 60 minutes of daily physical activity may be limited by a complex interaction between neighborhood social and physical environmental factors and the extent to which parents respond by constraining offspring outdoor play. The central hypothesis of this research is that modifiable factors in the neighborhood social and physical environment result in parental constraint of offspring outdoor play, which reduces overall physical activity during critical years of development. This research will use qualitative methods to generate a comprehensive understanding of how and which environmental factors play a crucial role in parental constraint of outdoor play and promote low levels of within-neighborhood physical activity. This ancillary study will recruit 32 parents/guardians of participants from the parent study, Translational Investigation of Growth and Everyday Routines in Kids (TIGER Kids) Study (USDA 3092-51000-056-04A), to participate in in-depth interviews. My ultimate goal is to use knowledge gained from this ancillary study to generate community-based interventions that will target neighborhood factors to successfully reduce parental constraints on outdoor play.

The aims of this ancillary study are:

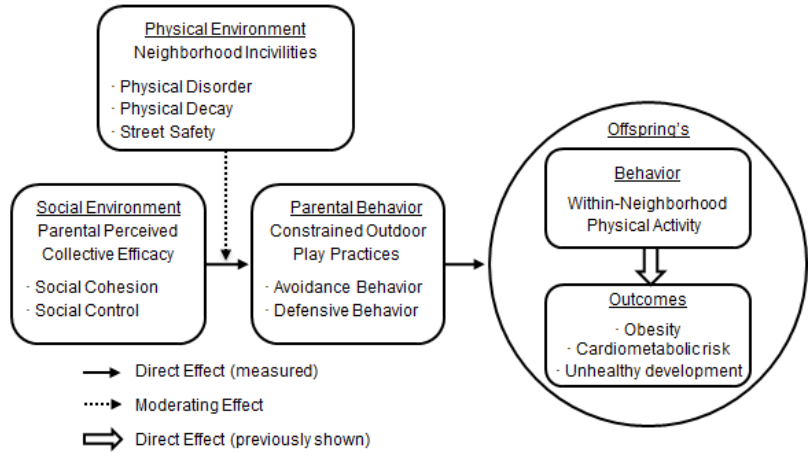
Aim 1: Implement qualitative methods (in-depth interviews) among parents/guardians living in varied neighborhood environments (low/high incivilities) to gain in-depth information and perspectives of the social environment's influence on constrained outdoor play practices.

A1a. Identify how parents/guardians experience neighborhood incivilities and whether/how incivilities influence perspectives shared during in-depth interviews (Aim 1).

B. Background

Play is so important to optimal child development that it has been recognized by the United Nations High Commission for Human Rights as a right of every child.[1] The neighborhood environment has become an important setting to achieve outdoor play, since time for free play has decreased during school hours.[1] Today's youth spend too little time playing outdoors, contributing to overall low levels of physical activity which has been linked to obesity, cardiometabolic risk and unhealthy development.[2] Neighborhood environmental factors may contribute to low levels of physical activity; however, results have been inconsistent.[3,4] These inconsistencies are due in part to (1) "conceptual mis-match" between environmental characteristics and physical activity domains (e.g., relating total physical activity, instead of within-neighborhood physical activity, to neighborhood characteristics) and (2) failure to examine mediators/moderators of environment-physical activity relationships such as parenting behaviors.[5] Perceived collective efficacy, which is a social environmental measure of social cohesion and control among neighbors, may influence physical activity opportunities for adults[6-8] and children.[3,9] For children and adolescents, parents may constrain their child's outdoor play in part because of their sense collective efficacy (Figure 2). My dissertation work suggests that this relationship may be modified by incivilities in the neighborhood physical environment, where, for example, graffiti and blighted property in the neighborhood exacerbate the problem.[10] This ancillary study will use qualitative methods to gain an in-depth understanding of the social environment's influence on parental constraint of outdoor play.

Figure 2: Conceptual Framework for the Proposed Research



Significance: This ancillary study will be performed among parents/guardians living in two distinct neighborhood types (low vs. high incivilities) to further understand how social environments and processes may differ across varied physical environments. This study is significant because although childhood obesity and unhealthy development are common, research exploring environmental influences on physical activity-related parenting behaviors is scarce, and the proposed pathway has not been explored in children or adolescents using qualitative methods. Thus, the results will inform community-based interventions that target modifiable social and physical environmental factors to increase neighborhood physical activity thereby promoting the healthy development of children and adolescents.

Innovation: This study is innovative in its scientific questions and hypotheses, which hold promise to shift the paradigm by focusing on the environmental triggers that may promote or impede children's physical activity. If parental constraint of outdoor play is the mechanism by which aspects of the neighborhood physical and social environment influence offspring's within-neighborhood physical activity, then interventions can be designed to address parent-imposed barriers to outdoor play.

Inclusion and Exclusion Criteria

This ancillary study will include 32 parents/guardians of TIGER kids participants who previously completed the parent study baseline (Y0) visit. Any parent/guardian of a TIGER Kids participant who completed baseline measurements is eligible for this ancillary project.

Inclusion Criteria:

- Child completed baseline measures (Y0) for the TIGER Kids Study.

Exclusion Criteria:

- Child did not complete baseline measures (Y0) of the TIGER Kids Study.
- Did not report a home address at the baseline (Y0) TIGER Kids study visit.
- Unwilling or unable to participate in an in-depth interview.

In addition to the exclusion criteria listed above, participants who refuse to sign an informed consent document will be excluded from the study. Consent will be obtained upon each participant's arrival at the Pennington Biomedical Research Center or community location [i.e. YMCA or East Baton Rouge Parish Library (EBPL) Branch] before participating in the in-depth interview. Furthermore, the principal investigator has the right to withdraw a participant from the study at any point for any reason.

Number of Subjects and Subject Timeline

32 parents/guardians of participants from the TIGER Kids parent study will be recruited for this ancillary study. All parents/guardians will be recruited after their child has completed the baseline (Y0) TIGER Kids study visit. Recruitment will begin July 1, 2017 and be completed by July, 2018.

Recruitment Methods

Parents/guardians will be recruited from the existing participants in the TIGER Kids parent study. Recruitment of parents/guardians will occur after the child has complete baseline (Y0) measures of the parent study. Contact information obtained from those who have already completed the baseline visit of the TIGER Kids parent study will be used to recruit for this ancillary study in-depth interviews. Furthermore, baseline data from the Y0 TIGER Kids study visit on socio-economic status, race, and neighborhood environment will be used to recruit parents from diverse demographic backgrounds and two distinct neighborhood environments (low vs. high incivilities). Consent will be obtained when the parent/guardian comes to Pennington Biomedical for their in-depth interview.

Study Timelines

Enrollment is currently underway for the TIGER Kids parent study, and will continue through March, 2018. Data collection for the two time-points of the parent study will continue through August 2019, however only baseline data from the parent study will be used for this ancillary study. The investigators estimate all baseline visits for the parent study will be completed by March 2018. Recruitment of parents/guardians for this ancillary study will be completed by July, 2018. All data collection will be completed by December, 2018.

Table 1: Two-year Study Timeline (Projected Start Date: July 2017)								
	2017		2018				2019	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Parent Study Recruitment and Y0 visits (ongoing since June 2016)								
Ancillary Study Recruitment								
Ancillary Study Data Collection (In-depth Interviews)								
Ancillary Study Data Analysis								
Ancillary Study Manuscript Development and Submission								

Consent Process

For this ancillary study, informed consent will be obtained from the parent/guardian of the TIGER Kids study who is willing to participate in in-depth interviews. Written informed consent will be collected in a private room located in Pennington Biomedical Research Center or a community location (i.e. YMCA or EBRPL branch) during the study visit at which the in-depth interview will take place. This visit will be a separate visits and subsequent to the parent study (TIGER Kids) Y0 baseline study visit. The study procedures will be explained to parent/guardian. They will be asked if they have any questions about the study and will be given adequate time to review and ask questions.

Study Endpoints

There is no primary endpoint this study. This study is qualitative and therefore aims to gather in-depth information from the participant to understand how the neighborhood environment may or may not impact their parenting decisions regarding their child's outdoor play.

Procedures Involved

Study Design: The overall strategy is to implement in-depth interviews among 32 parents/guardians of participants from the TIGER Kids Parent Study (USDA 3092-51000-056-04A). This ancillary study will be implemented among 32 parents/guardians from diverse neighborhood environments using purposeful sampling. We anticipate that a sample of 32 parents/guardians will be sufficient to reach saturation.

Qualitative Measurements: Semi-structured in-depth interviews will be conducted among TIGER Kids parents/guardians stratified by neighborhood environments (low and high incivilities). An interview protocol will be developed in collaboration with an expert in qualitative research (Dr. Griffith, project consultant). Interviewees will sign informed consent prior to data collection. Individual interviews will last approximately 1.5 hours including time for participants to complete a short demographic survey. Participants will receive an incentive of $25 for interview completion. All interviews will be taped and transcribed verbatim.

Data Analysis Plan

For this ancillary study, all transcribed interview data will be imported into the appropriate qualitative data software (e.g. NVivo10). One interview will be chosen for two trained staff members to code and establish an initial code-book. All coding discrepancies will be discussed until an initial codebook detailing code definitions is agreed upon. An additional interview will then be coded by two staff members to refine the codebook and inter-rater reliability will be calculated. Once a final coding protocol is established, all remaining interviews will be coded. A thematic analytic approach will be used to analyze participant responses within coded text segments for similarities and differences that

clustered to classify emerging themes.[42] All themes will be recorded in Microsoft Excel, and similar themes may be further grouped into broader thematic categories if necessary. Concise phrases that capture the overall meaning will be assigned to each theme. Themes will be sorted and compared between participants grouped in low vs. high incivility neighborhoods to determine if differences in responses between the two groups were present (Aim 1a).

Data Management and Confidentiality

The Contextual Risk Factors Laboratory, supervised by Dr. Broyles (co-investigator and Dr. Kepper's sponsor), will have primary responsibility for data collection, data management, manual data entry and data analysis. All electronic data will be stored in the secure Pennington database, with access given to only necessary, HIPAA certified staff. All hard copies of data will be stored in a secure, locked cabinet at Pennington Biomedical Research Center. Data collected at a community location will be securely transported to PBRC by trained staff. Access to data files can be made only with permission of the Academic Principal Investigator. Following transcription of the interviews, the original audio tapes will be destroyed. Data will be stored for 5 years following study completion.

Provisions to Protect the Privacy Interests of Subjects and Monitor the Data to Ensure the Safety of Subjects

This study does not involve more than minimal risk to participants. All data will be collected through non-invasive measurements, interviews. All interviews will be conducted in a closed, private room. Interviews do not contain sensitive items for ensure that the participants are comfortable responding. Only first names will be used during the interview. Data will be stored in a secure area and all study staff must be HIPAA certified. Following transcription of the interviews, the original audio tapes will be destroyed. Only pertinent study staff will have access to study data.

Withdrawal of Subjects

Participation is voluntary, so participants may withdraw from the study at any time. Data that have already been collected during the course of the interview from a withdrawn participant will be used, unless a specific request is otherwise received. Participants may be withdrawn from the study for the following reasons:

- Unwillingness on behalf of the participant to participate in the study or cooperate with study staff

Risks to Subjects

There are no foreseeable risks to participants in this study. The interviews will not include any sensitive topics that could make participants uncomfortable.

Benefits to Subjects

We cannot promise any direct benefits to the participant from participating in the in-depth interview, although barriers to children and adolescent's physical activity identified from the interview may inform community-based interventions or policy changes that may increase children's outdoor play and promote health.

Vulnerable Populations

This study does not involve vulnerable populations.

Sharing of Results with Subjects

Study results will not be shared with participants unless requested. If requested, only group summary data will be available.

Setting

In-depth interviews will be performed in a private room at Pennington Biomedical Research Center or at community location (i.e. YMCA or EBRPL Branch).

Resources Available

Maura Kepper, Ph.D, Principal Investigator, is a Postdoctoral Researcher at Pennington Biomedical. Dr. Kepper is a trained behavioral scientist with expertise in physical activity assessments, surveys and observational assessments of children's behaviors and environments related to children's health.

Stephanie Broyles, Ph.D., Sponsor, is an Associate Professor and Director of the Contextual Risk Factors Laboratory at Pennington Biomedical. Dr. Broyles is a trained biostatisticians and has expertise in exploring how the neighborhood environment impacts physical activity and health outcomes in pediatric populations.

Amanda E. Staiano, Ph.D., M.P.P., Co-Sponsor, is an Assistant Professor and Director of the Pediatric Obesity and Health Behavior Laboratory at Pennington Biomedical. Dr. Staiano is a developmental psychologist with expertise in epidemiological surveys of children's physical activity and screen-time and interventions to improve children's physical health.

Peter Katzmarzyk, Ph.D., Co-Sponsor, is a Professor and Marie Edana Corcoran Endowed Chair in Pediatric Obesity and Diabetes. Dr. Katzmarzyk has expertise in the epidemiology and public health impact of obesity and physical inactivity, and determining the relationships between physical activity, physical fitness, obesity and related disorders such as metabolic syndrome, cardiovascular disease and diabetes, particularly in children and youth.

Derek Griffith, Ph.D., Consultant, is an Associate Professor of Medicine, Health and Society at Vanderbilt University. Dr. Griffith is a leading social scientist focused on social influences on men's health and racial and ethnic health disparities. He has primarily used qualitative methods to understand the social, psychological and environmental determinants of health behavior and it is this expertise that he will lend to this ancillary study.

Prior Approvals

None.

Compensation for Research-Related Injury

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) will be available for this research study. In the event of injury or medical illness resulting from the research procedures, participants will be referred to a treatment facility.

Economic Burden to Subjects and Compensation

All participants will be responsible for bearing the cost of transportation to and from the in-depth interview location. Interviews will be held at Pennington Biomedical Research Center or at community location (i.e. YMCA or EBRPL Branch), whichever is more convenient for the participant in order to cut down on these costs. Furthermore, all participants will receive $25 in compensation upon completion of the in-depth interview to offset these costs. The check will be requested from the LSU payroll department once the participant completes the study. It is expected that it will take 3-4 weeks for the check to arrive at Pennington Biomedical Research Center. The payment will then be mailed to the participants your home address.

Drugs or Devices

Not applicable.

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