A Correlational Study Between Blood Pressure and Body Mass Index in 10-12 Year Old Children

Dana Zahran

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A Correlational Study Between Blood Pressure and Body Mass Index in 10-12-Year-Old Children

by

Dana Zahran

An Honors Capstone

submitted in partial fulfillment of the requirements

for the Honors Diploma

to

The Honors College

of

The University of Alabama in Huntsville

04/22/19

Honors Capstone Director: Dr. Thuy Lynch

[Signature]

04/24/19

[Signature]

04/24/19

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4/24/19

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5/1/19

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Dana Zehran
Student Name (printed)

Dana Zehran
Student Signature

04/22/19
Date
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______________________________
Student Name (printed)

______________________________
Student Signature

______________________________
Date
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Acknowledgement

I would like to thank Dr. Thuy Lynch for allowing me to join her research to further knowledge on the increasing rates of BMI in children and its possible effects on their health. This research not only challenges me as a researcher to stress the importance of proper dieting and exercise in children but raises awareness of the possible disease factors associated with obesity in childhood. I would also like to thank Dr. Ann Bianchi for her support throughout this entire process. Finally, I would like to thank Dr. Nagendra Rao Thotakura for his support and approval of this research in a clinical setting.
Abstract

Background: With obesity on the rise in children, the risks that are associated with increased body mass index (BMI) are essential to research to prevent future medical complications. Elevated BMI in children can extend into adulthood with adverse consequences such as elevated levels of insulin, lipids and blood pressure. If a link between BMI and blood pressure is determined, increased BMI in children will become a primary indicator for providers to monitor body mass and blood pressure at a younger age. Purpose: The purpose of this study is to determine the relationship between blood pressure and body mass index in children ages 10-12 and compare the findings with results from a feasibility study conducted in a school setting by the faculty mentor. Methods: For this cross-sectional, descriptive study, a convenience sample of thirty 10-12 year-old children were included. The participants were recruited from pediatric clinics in the southeastern area. Parent participants completed a demographic questionnaire. Child participants’ blood pressure, height, and weight were measured. Results: A total of ten children participated in the study. Of the ten children, there was one African American male, three African American females, three white males, one white female, one Latino male, and one Latino female. From the data collected, a trend of elevated BMI and blood pressure existed with the African American females and white males. Discussion: Both the clinic setting and school setting, suggest a possible correlation between BMI and blood pressure. However, more data needs to be collected on a greater population to further conclude a definite correlation. Implications: In both the clinic and school setting, the nurses at the clinic were not using the guidelines set by the American Academy of Pediatrics to check for elevated blood pressure, stage 1 hypertension, or stage 2 hypertension in the children. A greater emphasis on monitoring children’s blood pressures and determining whether they are elevated is important to implicate prevention of hypertension in clinics and schools.
Introduction

With obesity on the rise in children, the risks that are associated with increased BMI are essential to research to prevent future medical complications. Overweight children are 4.5 to 2.4 times as likely to have elevated systolic blood pressure and diastolic blood pressure (Ying-xiu et al., 2013). Prevention of excessive weight gain in children can lead to a decreased risk of chronic diseases in adult life (Ying-Xiu et al., 2013). Dietary changes that can decrease blood pressure include reduction in cholesterol, saturated fat, trans fat, and added sugars. The consumption of added sugars has greatly increased with children. The increase of added sugar in a child’s diet was found to increase diastolic blood pressure by about 0.02 millimeters of mercury (mmHg) per gram of added sugars (Kell et al., 2014). Isolated hypertension in diastolic blood pressure is common in children at risk for hyperlipidemia (Kell et al., 2014). Hyperlipidemia is a main risk factor for both atherosclerosis and cardiovascular disease (Kell et al., 2014). Obese children have an increased chance of becoming obese adults with adverse levels of insulin, lipids, and blood pressure (Freedman et al., 2012). If a correlation is found between BMI and blood pressure, increased BMI in children will become a primary indicator for providers to encourage weight loss and to lower blood pressure at a younger age to prevent the formation of hyperlipidemia and atherosclerosis (Freedman et al., 2012).

Ethnicity may affect which children are more at risk for hypertension due to increased BMI. For example, Turkish children showed a more dramatic increase in systolic blood pressure with increased BMI as compared to Dutch children (LA de Hoog et al., 2012). On the other hand, systolic blood pressure was high for Moroccan children with both extremely low BMI values and high BMI values (LA de Hoog et al., 2012). This finding indicates that in addition to BMI, ethnicity may correlate with high blood pressure and certain populations may be at greater
risk. For these populations, studies that attempt to correlate effects of obesity to those that are at risk for developing chronic diseases provide valuable information to reduce those diseases. Flynn and colleagues (2017) updated the clinical practice guidelines from The Fourth Report published in 2004 that provides the parameters to diagnose, evaluate, and treat high blood pressure in children and adolescents (Flynn et al., 2017). The clinical practice guidelines are endorsed by the American Heart Association (AHA) and will be used in this study.

**Purpose**

By determining the relationship between blood pressure and body mass index in school-aged children, specifically in the 10-12-year-old age group, further recommendations to prevent or decrease the risk of cardiovascular disease or other chronic diseases can be made.

**Research questions**

1. Is there an association between blood pressure and body mass index in 10-12-year-old children?
2. Are there any differences in blood pressure and body mass index in children from a school setting compared to children screened in a pediatric clinic?

**Review of Literature**

A couple of studies have been performed seeking to correlate skin fold thickness, lipid levels, and blood pressure. In 2017, Flynn and colleagues, updated the parameters to define elevated blood pressure, which were used in this study. Although this study did not specifically address skin fold thickness and lipid levels, the research already conducted on these topics have provided more evidence of the effects of obesity on blood pressure.
In the systematic review performed by Flynn and colleagues (2017), a systematic search and review of literature was performed to update the 2004 guidelines regarding screening and management of blood pressure in children and adolescents. The initial search included articles published between January 2004 and August 2015. The process of the review followed the recommendations of the Institute of Medicine for Systemic Reviews. The findings of the Systematic Review define parameters for elevated blood pressure in children as systolic and diastolic blood pressure $\geq 90$th percentile to $<95$th percentile or $120/80$ mmHg to $<95$th percentile. Percentages are based on children of the same age, sex, and height. Stage 1 hypertension is defined as $\geq 95$th percentile to $<95$th percentile + $12$ mmHg, or $130/80$ to $139/89$ mmHg (whichever is lower), and Stage 2 hypertension is defined as $\geq 95$th percentile + $12$ mm Hg, or $\geq 140/90$ mm Hg (whichever is lower). Obesity is defined as children with a body mass index between the $95^{th}$ and $98^{th}$ percentiles. The strengths of this study included the articles reviews were not chosen based on authorship and that the study is an update from the 2004 guidelines. The limitation of the study is that pediatric literature is not standardized, as there is a lower prevalence of hypertension in children and lack of adverse events in children (Flynn et al., 2017).

A cross-sectional study completed in Birmingham, Alabama explored the association between added sugar consumption in children, blood pressure, and fasting blood lipids. Data was collected from October 2004 to December 2008 as part of the AMERICO study. Participants included 320 children from seven to twelve years of age. They wore accelerometers to measure physical activity and performed Dual-energy X-ray absorptiometry (DXA) scans. The results indicated added sugars were positively associated with diastolic blood pressure and serum triglycerides. Strengths of the study included a diverse cohort in terms of race and ethnicity, and
the ability to isolate the association between dietary sugars, blood pressure, and blood lipids by controlling for lifestyle. Limitations of the study included the results may not be generalized to other geographic contexts, and it is not possible to determine how the observed relations may change throughout the life span (Kell et al., 2014).

In a study completed by Ying-Xui et al. (2013) a descriptive study was completed to examine the association between BMI and skinfold thickness with blood pressure in 12-year-old children from four schools in Shandong province. The overall prevalence of obesity was found to be 11.52%. The prevalence of high blood pressure was 16.16% in boys and 15.79% in girls. BMI and skinfold thickness were significantly (p < 0.01) related to systolic blood pressure. Strengths of the study included appropriate protocol to select blood pressure cuff size and genders were analyzed separately. Limitations include possible white coat syndrome and that the blood pressure was recorded as an average over two measurements in one session only (Ying-Xiu et al., 2013).

In a cross-sectional study, Wirix and associates (2017) explored the association between added sugar consumption in children, blood pressure, and fasting blood lipids in the Netherlands. Blood pressure was measured three times consecutively on the right arm after five minutes of rest while seated. The strengths of the study included comparison of hypertensive overweight children, normotensive overweight children, and normotensive non-overweight children. Limitations of the study included blood pressure measurement was only taken on one occasion and there was no ambulatory blood pressure monitoring (Wirix et al., 2017).

A cross-sectional study completed in a Bogalusa community in Washington Parish, Louisiana examined whether the prevalence of obesity among children and adolescents is
accompanied by increases in blood pressure levels. The mean of six measurements of blood pressure were used in the analyses. The authors found that the prevalence of obesity increased from six to seven percent during the twenty-year study. The levels of BMI were positively associated with blood pressure in each of the examinations. Controlling for BMI showed that only 60% of children as expected had high levels of blood pressure. Strengths of the study included differentiation between age, gender, and height and the length of the twenty-year study. Throughout the twenty years, a protocol was used in the selection of cuff size was followed. Limitations of the study included all blood pressure readings were taken on one visit and it is estimated one-third of children were measured using bladders that were too large (Freedman et al., 2012).

In order to avoid limitations experienced in other studies, appropriately sized cuffs and bladders will be used for each participant. To determine any possible correlation between elevated blood pressures with different ethnicities, a demographic questionnaire will be given to each participant. In addition, genders will be recorded to further investigate a possible association between genders and blood pressures.

**Theoretical Framework**

The Mosaic Theory proposed by Dr. Irvine Page remains a prominent theory in considering the causes of hypertension (Page, 1967). As described earlier, ethnicity may play a role in determining individuals who are at greater risk in developing hypertension. Page proposed different factors, such as genetics, environment, adaptive, neural, mechanical, and hormonal factors that may influence blood pressure. Individuals with a genetic predisposition to elevated blood pressure, sustain hypertension after a factor, such as added sugars in the diet, raises the blood pressure. In addition, Page attributes hypertension to environmental factors.
The other factors that Page proposed surround the adaptive responses of the body to stressors that lead to hypertension. The adaptive responses include the nervous system, cardiovascular system, hepatic system, renal system, and endocrine system. The systems cycle and work together in an attempt to keep the body in a homeostatic state. The nervous system releases hormones such as adrenaline and noradrenaline to constrict and dilate vessels in response to blood pressure changes. If the body is experiencing constriction of the vessels, the blood pressure is elevated. In a state of vasodilation, the blood pressure decreases. The cardiovascular system also works in an attempt to keep the body in a state of equilibrium. Page described that the force of a heartbeat can increase, thereby increasing blood pressure. The hepatic system is also involved. The liver increases vascular reactivity when the body is hypertensive. In addition, the endocrine system releases hormones, working with the nervous and renal system to stabilize the blood pressure. The endocrine system also reacts to vascular damage, which can increase the blood pressure. The renal system releases hormones such as renin-angiotensin to decrease hypertension (1967).

Page’s Mosaic Theory entails the critical feedback loop that the body cycles through to regulate blood pressure. Not only does Page mention factors that increase the risk of hypertension, but he also describes systems that are involved in regulating hypertension in the body if it occurs. This indicates that blood pressure is a complex, interrelated concept that can alternate the outcomes of major organs in the body. With children that are hypertensive or obese, it is helpful to consider the Mosaic Theory and attempt to determine if any of the feedback loops are occurring as a mechanism to compensate for the elevated blood pressure and increased cardiac output. This information can lead to further studies measuring hormone levels and organ function in children that are hypertensive (1967).
Methodology

Population, Sample and Setting
A convenience sample of ten participants were included in this study. The child participants included their parents as participants (10 parent participants). Participation was limited to one parent. The participants were essentially healthy 10-12-year old children. Both males and females of various racial and ethnic diversities were included. Participants were recruited from Alabama Children’s Clinic in Madison and Huntsville, Alabama. Children selected were able to assent to participation and understood the assent form written in English. Children also received consent from their parents, who understood the consent form written in English.

Data Collection
A child (10-12 years of age) and parent who made a wellness visit to the clinic were asked to participate in the study. After assent and consent from both the child and parents, respectively, had been received, the parents were asked to complete a Demographics Questionnaire form (see Appendix C). Height, weight, and a blood pressure reading for each child participant were measured and recorded by the PI, Dana Zahran (see Appendix D). Data collection took place in a private patient room within the clinic. Parents of each child participant were present during data collection. The pediatrician’s office nurse was present during data collection. The pediatrician was available during the time of data collection and was notified of any blood pressure elevations.

Research Design
This study is a correlational study that develops research on the relationship between blood pressure and body mass index in children aged 10-12-years old.

Measures/Instruments
Height and weight: Height was measured with a stadiometer (Seca 213). Height was recorded to nearest ¼ inch. Weight was measured with the SECA 803 digital body weight scale. The standardized procedures for body weight allow for the use of an electronic digital scale that measures to the nearest 100 grams (Heyward & Wagner, 2004). With these measurements, BMI was calculated using the standard equation of weight in pounds divided by height in inches squared and multiplied by 703 (Centers for Disease Control and Prevention, 2018).

Blood pressure: Blood pressure was measured with a GE® Dinamap Pro 100 series with each patient seated and their right arm rested on the arm rest at the level of their chest. An appropriate-sized cuff was used for each child and placed on the upper right arm.

Demographics Questionnaire: The questionnaire was given to each parent providing assent for their child to participate. The questionnaire includes the age, gender, race, and ethnicity of the participating child. Questionnaire available in Appendix C.

Procedure

A child (10-12 years of age) and parent who made a visit to the clinic during the period of data collection were asked to participate in the study. After assent and consent from both the child and parents, respectively, had been received, the parents were asked to complete a Demographics Questionnaire form (see Appendix C). Height, weight, and blood pressure readings for each child participant were measured and recorded by the PI, Dana Zahran (see Appendix D). Data collection was taken place in a private patient room within the clinic. Parents of each child participant were present during data collection. The pediatrician’s office nurse was also present during data collection. Elevated blood pressure readings were reported to the pediatrician’s office nurse. The pediatrician was available during the time of data collection and was notified of any blood pressure elevations.
Results

A total of ten children participated in the study. Of the ten children, there was one African American male, three African American females, three white males, one white female, one Latino male, and one Latino female. From the data collected, a trend of elevated BMI and blood pressure existed with the African American females and white males. Both populations had three children. Of the three children, the child with the lowest BMI had the lowest blood pressure. The highest blood pressures collected were both white males with a blood pressure of 118/70. The lowest blood pressure collected was an African American female with a blood pressure of 98/58. Her BMI of 14 was the lowest collected in the study. The data collected is presented in Figure 1.

Limitations

With only ten participants in the study, there is not enough data to generalize to populations. Only two populations had more than one child represent that demographic, limiting the comparisons that can be made with the differences in blood pressures between different races. Since the data was taken in a pediatric clinic, many of the children reported feeling nervous. The nerves may have skewed blood pressure reading, slightly elevating them. A few of the wellness visits had children that were taking medications for attention-deficit/hyperactivity disorder. It was not studied in this research; however, the dosage of medications and management of the disorder may have affected the children’s blood pressure readings.

Discussion

With the data collected, there is evidence of a possible correlation between blood pressure and BMI. The children with the lowest BMI had the lowest blood pressures in the study. According to the American Academy of Pediatrics guidelines for screening of high blood
pressure, none of the children participating in the study had an elevated blood pressure or a blood pressure greater than the 90\textsuperscript{th} percentile for their age group and height.

A comparison with the faculty advisor’s feasibility study on children aged 10-12 in a school setting, showed that with greater BMI samples, high blood pressure readings could be seen. The highest BMI result in the school setting study was 35.2 with a blood pressure of 154/85. This blood pressure would fall under stage 2 hypertension according to the American Academy of Pediatrics guidelines. The lowest BMI in the school setting study was a BMI of 13.4 with a blood pressure of 117/54, which was not the lowest in the study.

Both the clinic setting and school setting, suggest a possible correlation between BMI and blood pressure. However, more data needs to be collected on a larger population to further conclude a definite correlation.

**Implications to Nursing Practice**

In both the clinic and school setting, the nurses at the clinic were not using the guidelines set forth by the American Academy of Pediatrics to check for elevated blood pressure, stage 1 hypertension, or stage 2 hypertension in the children. A greater emphasis on monitoring children’s blood pressures and checking whether they are elevated is important to implicate to prevent hypertension in clinics and schools. If there is an elevated blood pressure, patient and parent education can be enforced to reduce risk of hypertension when the child ages.

**Conclusions**

The study indicates that further research needs to be conducted to establish a correlation between blood pressure and BMI. In further studies, the effects of attention deficit medications and possible nervousness of being at the doctors need to be accounted for. In the study, the
results showed that lower BMI trended in lower blood pressures. A further study could follow children who have changes in their BMI and investigate the effect on their blood pressure readings. With only one child representing the male Latino population, female Latino population, male African American population, and white female population this study cannot distinguish differences in blood pressures based on race and ethnicity. Future research on blood pressure related to demographics could reflect the impact of race and ethnicity on blood pressure in children.

**Dissemination of Scholarly Work**

- Fifth Annual Research Horizons Day Poster Session: March 14, 2019
  - Title: "A Correlational Study on Blood Pressure and Body Mass Index in 10-12 Year-Old Children."
  - Location: Charger Union at the University of Alabama in Huntsville (UAH)
  - Awarded first place in Undergraduate College of Nursing
References


Figures

Figure 1: BMI and Blood Pressure in 10-12-Year-Old Children Chart

Figure 2: BMI and Blood Pressure in 10-12-Year-Old Children Table

<table>
<thead>
<tr>
<th>Age</th>
<th>African American Male</th>
<th>Female</th>
<th>White Male</th>
<th>Female</th>
<th>Latino Male</th>
<th>Female</th>
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<td>60</td>
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<td>23</td>
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<td>12</td>
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</tr>
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<th>Age</th>
<th>African American Male</th>
<th>Female</th>
<th>White Male</th>
<th>Female</th>
<th>Latino Male</th>
<th>Female</th>
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</tr>
<tr>
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<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
## Correlational Study Between Blood Pressure and BMI

Figure 3: Demographics of Participants

<table>
<thead>
<tr>
<th></th>
<th>Number of Children</th>
<th>Percentage of Children</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AGE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 Years Old</td>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td>11 Years Old</td>
<td>7</td>
<td>70%</td>
</tr>
<tr>
<td>12 Years Old</td>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td><strong>GENDER</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>5</td>
<td>50%</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>50%</td>
</tr>
<tr>
<td><strong>RACE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>4</td>
<td>40%</td>
</tr>
<tr>
<td>Caucasian/White</td>
<td>4</td>
<td>40%</td>
</tr>
<tr>
<td>Multiracial</td>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td><strong>ETHNICITY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latino/Hispanic</td>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>Non-Latino/Non-Hispanic</td>
<td>8</td>
<td>80%</td>
</tr>
</tbody>
</table>
November 14, 2018

Dana Zahran
UAH Honors College Nursing Student
The University of Alabama in Huntsville
301 Sparkman Drive
Huntsville, AL 35899

Dear Ms. Zahran:

This letter is in support of your Honors College project entitled “A Correlational Study on Blood Pressure and Body Mass Index in 10-12 Year-Old Children”. I understand that your faculty advisor, Dr. Thuy Lynch, will help provide guidance with your project.

I am granting you access to my clients (children and their parents/guardians) starting December 1, 2018 and ending on May 30, 2019 in order to recruit participants and collect data for your project. The participants will include children, ages 10-12, whom visit the Huntsville Children’s and Madison Children’s clinics.

Sincerely,

[Signature]

Dr. Nagendra Rao Thotakura
Appendix B

Verbal Script for Recruitment

After the nurse has completed her initial assessment, the PI, Dana Zahran, will introduce herself and say the following:

“Hello, it’s nice to meet you. My name is Dana Zahran and I am with the University of Alabama in Huntsville’s Honors College. I am doing a research study on children aged 10-12 years old that will look at their blood pressure and BMI. I want to see if there is a relationship between the two. If you would both like to participate, I will take (child’s name)’s blood pressure twice and write down their height and weight. If you agree, I also have this demographic questionnaire that (parent’s name) will fill out. Participating is your choice, and if you do not want to participate that is okay. If you would like to participate, I have a form that both of you need to sign, letting me know that it is okay to include you in this study.”
Appendix C
Demographic Questionnaire

Please fill out the following information as part of your participation in this study. It should take approximately 3 minutes to complete this questionnaire. Your answers will be confidential.

1. Age: __________
2. Gender: M________ F________

3. Race:
   __________ African American/Black
   __________ Asian/Pacific Islander
   __________ Caucasian/White
   __________ Multiracial
   __________ Other, please indicate

4. Ethnicity:
   __________ Latino/Hispanic
   __________ Non-Latino/Non-Hispanic
Appendix D
Data Collection Sheet

Gender: _______________ Male ________________ Female
Age: _______________
Height ______________ inches
Weight ______________ pounds
BMI ______________

Blood Pressure #1______________________

Blood Pressure #2______________________
Appendix E

Consent Form: A Correlational Study on Blood Pressure and Body Mass Index in 10-12-Year-Old Children

You are invited to participate in a research study about blood pressure in children. This study is designed to help us to better understand the relationship between blood pressure and body mass index in 10-12-year-olds.

The primary investigator is Dana Zahran from the College of Nursing at the University of Alabama in Huntsville. Parental consent is required for any child under the age of 18.

PROCEDURE TO BE FOLLOWED IN THE STUDY: Participation in this study is completely voluntary. If you do not choose to participate, there will be no effect on the treatment your child receives. Your relationship with all of the staff members will not be affected either. Once written consent is given; you will be asked to complete a Demographics Questionnaire form. Height, weight, and two blood pressure measurements of your child will be taken. Data collection will take place in a private patient room within the clinic. The nurse will be present during this data collection. High blood pressure readings will be reported to the nurse. The pediatrician will be available during the time of data collection and will be notified of any blood pressure elevations. This session will take approximately 15 minutes.

DISCOMFORTS AND RISKS FROM PARTICIPATING IN THIS STUDY: There are no physical risks in this study. Your child may feel embarrassed sharing weight measurements; however, all data will remain anonymous and your child will be informed. Blood pressure measurement may feel uncomfortable. I will explain that the cuff will feel like a “tight squeeze” on the arm during measurement. All data will be collected in a private and secure room within the clinic.

EXPECTED BENEFITS: There will be no direct benefits from this research as this is a study of whether there is an association of blood pressure and body mass index in children.

INCENTIVES AND COMPENSATION FOR PARTICIPATION: Your child will receive two scented pencils, valued at 5 dollars, if they choose to participate.

CONFIDENTIALITY OF RESULTS: No names will be recorded on the data collection sheets. All information will be anonymous. Data will be secured at UAH, safely protected.
FREEDOM TO WITHDRAW: You are free to withdraw your child from the study at any time. I have the right to remove any participant from the session without regard to consent.

CONTACT INFORMATION: If you have any questions, please ask me now. If you have questions later on, you may contact me, Dana Zahran, at dmz0002@uah.edu or my Supervising Faculty, Dr. Thuy Lynch at Thuy.Lynch@uah.edu or 256.824.4880. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (IRB) at 256.824.6992 or email the IRB chair Dr. Bruce Stallsmith at irb.@uah.edu.

If you agree to participate in our research please sign and date below.

This study was approved by the Institutional Review Board at UAH and will expire in one year from <date of IRB approval>.

____________________________
Name (Please Print)

____________________________
Signature

____________________________
Date
Appendix F
Child Assent Form

Title: A Correlational Study Between Blood Pressure and Body Mass Index in 10-12-Year-Old Children

IRB Protocol No.: E2018134

Sponsor: The University of Alabama in Huntsville

Investigator: Dana Zahran, UAH Student Nurse

The researcher named above is doing a research study.

These are some things we want you to know about research studies:
I am asking you to be in a research study. Research helps us learn new things and figure out relationships between two things.

It is your choice whether or not you want to be in this study. You can say Yes or No. Whatever you decide is OK.

Why am I being asked to be in this research study?
You are being asked to be in the study because I want to know how your weight and height can affect how your blood pumps through your body. I am trying to find out how 10-12-year-old children are affected by body size and blood pressure.

What is the study about?
The study is about how weight and height affect children’s health. This research is important because it can help researchers understand the effects of weight and how blood pumps through the body. All of the study activities will take about 15 minutes to complete. The study will take place in a private room in your clinic.

What will happen during this study?
If you agree to be in this study, you will:

• Be escorted by the clinic nurse to a private room where the study activities will take place.
• Have your weight, height, and blood pressure measured.
• Get a set of scented pencils for participating.

Will the study hurt?
Taking part in these tests will not hurt. If you not want to do any of the tests, you do not have to participate.
What else should I know about the study?
You do not have to do anything that you do not want to do. You may feel uncomfortable when the blood pressure is being taken, but there should be no pain.

What are the good things that might happen or benefits?
People may have good things happen to them because they are in a research study. These are called “benefits”. You will probably not receive any specific benefits from being in this research study. However, researchers may be able to learn important facts about children that are not already known.

What if I don’t want to be in this study?
Even though your parents have given us permission to contact you about this project, you do not have to participate if you don’t want to. This is completely up to you.

Who should I ask if I have any questions?
If you have any questions about this study, you or your parents can call Dana Zahran (256) 527-8822, UAH faculty supervisor, Dr. Thuy Lynch at (256) 824-4880 or email at Thuy.Lynch@uah.edu, or the IRB Chair, Dr. Bruce Stallsmith at (256) 824-6992 or email at irb@uah.edu.

Do I have to be in the study?
No, you do not have to be in the study. Even if you say yes now, you can change your mind later. It is up to you. No one will be mad at you if you don’t want to do this.

Now that I have asked my questions and think I know about the study and what it means, here is what I decided:

________ OK, I’ll be in the study. ________ No, I do not want to be in the study.

The researcher has told me about the research. I had a chance to ask questions. I know I can ask questions at any time. I want to be in the research.

If you sign your name below, it means that you agree to take part in this research study.

_____________________________  Age  ______________________
Your Name (Printed)  _____________________  Date

_____________________________
Your Signature  _______________________

_____________________________
Signature of Witness  ___________________

_____________________________
Signature of Person Obtaining Consent  ___________________
