Resendes, Erica. Changes in Health Knowledge and Lifestyles After Participating in a Research Study. Master of Science (Clinical Research Management), December, 2014. Pp. 59, Tables 16, Figures 7, Bibliography, Titles 19.

Advancements in health care would not have been possible without clinical research and more importantly those participants who volunteered. In order to continue this path of improvement, it is important to tackle issues of problematic recruitment and encourage more individuals to consider participating. Benefits associated with clinical research are a major driving force behind an individual's decision to participate. This study examined a different type of benefit, one that is not in the primary aim of the study. By highlighting such benefits, the public's perceptions of clinical research can be broadened, encouraging more individuals to consider participating. To assess these benefits, a one-time survey was completed by a parent/legal guardian of a child who participated in one of two previous research studies. The survey included questions from the initial studies to serve for comparison purposes. Results demonstrated that since completing the study a total of 34 (55.7%) parents/legal guardians reported a change in the child's diet, while 43 (70.5%) reported a change in the child's physical activities. When comparing responses (pre vs post), parents/legal guardians at the time of the follow- up study were more likely to make their child eat healthy and exercise regularly as well as describe their child as not being overweight. Lastly, a total of 42 (84%) of parents/legal guardians reported that they would be likely to participate in future studies as well as let their child participate in future studies.

CHANGES IN HEALTH KNOWLEDGE AND LIFESTYLES AFTER PARTICIPATING IN A RESEARCH STUDY

PRACTICUM REPORT

Presented to the Graduate Council of the
Graduate School of Biomedical Sciences
University of North Texas Health Science
Center at Fort Worth
In Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By

Erica Resendes, B.S.

Fort Worth, Texas

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ACKNOWLEDGEMENTS

Foremost, I would like to express my gratitude to my Major Professor, Dr. Kimberly Fulda, for allowing me this opportunity to work alongside her and her staff. I feel extremely lucky to have been paired with a mentor who is thoroughly passionate about her work and who was invariably patient and willing to help me. Without the valuable information she has provided me, along with her inspiring guidance and encouragement, completing this practicum would have been all the more difficult. I would also like to thank Michelle Lee, Dr. Anna Espinoza and Dr. Nusrath Habiba who further encouraged me through this process as well as aided me in learning all aspects of clinical research. The overall internship experience was an incredibly educational opportunity, which I am perpetually grateful for.

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An immeasurable thank you goes out to all of those individuals who willingly completed my survey and made the completion of this study possible. Your contribution to the scientific community does not go unnoticed.

Lastly, I would like to thank my family and friends who have always supported me and provided me with unconditional love and care. They continue to stand by me through the good and the bad and are instrumental in instilling my confidence. Words could never fully express my sincere gratitude.

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CHAPTER I

INTRODUCTION

My clinical research practicum began on June 1st, 2014 and was completed December 5, 2014. During that time I was paired with Dr. Kimberly Fulda, Associate Professor in the Department of Family Medicine and the Associate Director of the Primary Care Research Center. The Primary Care Research Center is located on the 7th floor of the EAD building at the University of North Texas Health Science Center. The Primary Care Research Center was developed to generate research to improve primary care and public health issues for not only the North Texas population but ultimately the nation. Although improvement in healthcare can be done without research and its generated measurements, research is vital as it can advance improvements at a faster and more efficient rate (Campbell, Braspenning & Hutchinson, 2003). The Primary Research Center has developed an innovative approach to clinical research by building both internal and external collaborative partnerships as a way of implementing research into a clinical setting. By using this approach they hope to gather knowledge that can be applied to a wide range of individuals and can be incorporated into future clinical practice (UNTHSC, 2014).

Dr. Kimberly Fulda served as the major professor and principal investigator for my clinical research practicum project. The study, entitled "Changes in Health Knowledge and Lifestyle after Participating in a Research Study" was conducted by surveying subjects over the phone, who had previously participated in either study titled "Psychosocial and Physiological Predictors of Type 2 Diabetes Mellitus Risk among Children Aged 10-14" or "Factors

Associated with Being at Risk for Type 2 Diabetes among Mexican American and Mexican Children".

The aim of this follow-up study was to assess the participants' self-reported benefits subsequent to participating in one of the two studies, specifically, by addressing the following questions:

1.) Did participating in the study improve the parent's recognition of their child's current health?

2.) Did the child make any strides in improving lifestyle behaviors, specifically focusing on diet and exercise, as reported by the parent?

3.) How likely is the parent to participate or have their children participate in future studies?

In the two previous studies, parents/legal guardians and their children received results for the following: risk for depression, cholesterol, liver function, blood sugar and blood pressure. The results were classified for each child participant as being either normal or abnormal. The goal of this study was to assess if these study results helped improve the parent's/legal guardian's knowledge regarding their child's current health status. Secondly, the goal was to also understand if this knowledge had any effect on the child's daily activities such as diet and exercise. By improving awareness, individuals can start making changes in their lifestyles at an early age. Early intervention may help prevent type 2 diabetes along with a number of associated secondary diseases that could affect their adult lives (Ogden, Carroll & Flegal, 2008). Lastly, the long-term goal was to highlight these benefits and help motivate future individuals, especially children, to consider participating in clinical research.

My role for this study was 'student investigator'. My responsibilities included developing the aims of the study, writing a proposal thoroughly detailing the study, creating all documents

including a survey, cover letter and protocol synopsis, obtaining IRB approval, recruiting past participants over the phone, conducting data entry using SPSS, and analyzing data.

CHAPTER II:

BACKGROUND AND LITERATURE

Clinical studies are designed to benefit healthcare by answering questions regarding treatments, diagnoses, and prevention methods. Although clinical studies are beneficial to the companies developing medications, along with providing hope for future patients, they can be equally beneficial to the participants in ongoing studies (Falconer et al., 2009). According to the Food and Drug Administration (FDA) some of the benefits include gaining access to potential treatments before they are available on the market and having access to medical care for a number of conditions being studied. When conducting a literature search regarding benefits associated with being a study participant, it was surprising to discover such a wide range of benefits linked to an even wider range of studies. The National Institutes of Health (NIH) acknowledges that it is important to present this information as a way to increase the public's understanding of clinical trials as they may be unaware of these benefits and therefore not as willing to consider participating (Bower et al, 2009).

A major reported issue in completing a clinical study has to do with problematic recruitment of study participants. Problematic recruitment can lead to many negative effects, including incomplete data collection, possible increased costs, or the need to extend the duration of the study (Hunninghake, Darby & Probstfield, 1987). In previous research attempting to address barriers pertaining to recruitment, it was found that potential survey participants

hesitated in enrolling because of their "uncertainty in the experimental nature of clinical trials" (Goyal et al., 2012). It is also common for participants to believe that involvement in a clinical study produces no direct personal benefits and also requires them to be subject to certain risks (Chue, Moody, Steeds, Townend & Ferro, 2011). However, there are a number of reports dating back to as early as the 1980's that highlight positive effects associated with health outcomes for study participants (Goyal et al, 2012).

As mentioned above, researchers have noted a wide range of benefits associated with study participation. Most of these benefits are the primary aim of the study, meaning that researchers will introduce a therapeutic drug or lifestyle intervention/ education program to the participant in hopes of improving their health. This type of benefit experienced by study participants may be largely explained by the term "trial effect", essentially a direct consequence of the clinical study. This is an instance where participants involved in a clinical study experience a more favorable outcome, as compared to a control group of non-study participants receiving the same type of care (Brauholtz, Wallace & Ward, 2001). In a study published in 2012, researchers were interested in investigating 'trial effect'. These researchers documented outcomes associated with chemotherapy regimens given in the context of a clinical study and compared them to outcomes associated with a non-study control group receiving the same regimen. Results showed a significantly lower risk of death and improved survival rate in the study subgroup. While the researchers conducting the study could not explain the exact mechanism behind such reported outcomes, they believe that the improvement in the participant's quality of living may be related to increased patient compliance, increased follow-

ups as stated in the study's protocol, and access to new or improved medical services (Goyal et al., 2012).

Although improved health outcomes are typically the primary goal for clinical studies, participants may often experience unexpected benefits. Incidental findings are defined as information that was discovered during the course of research with potentially significant health importance. These findings are beyond the aims of the study and can lead to positive health interventions (Wolf, Paradise & Caga-anan, 2008). In a study carried out at the University of North Texas Health Science Center, subjects were recruited originally to assess disparities in cardiovascular health. Computed tomography (CT) scans were used for research purposes and ended up revealing 246 clinical findings in a total of 169 asymptomatic participants. The report detailed specific situations including a 66-year-old man whose CT scan showed an enlarged spleen. After being referred to a primary care physician for this matter, he was eventually diagnosed with leukemia for which he received care outside of the study. When the researchers performed their first year follow-up, the participant reported that he was cancer-free (Espinoza, Malone, Balyakina, Fulda & Cardarelli, 2014). Although these incidental findings usually pertain to only a small minority of participants, they can help to improve the lives of participants who were once thought to be "healthy", even beyond the completion of the clinical study (Falconer et al., 2009).

While there are numerous articles published referencing benefits study participants received from participating in a clinical study, most focus on benefits received from a study involving an investigational drug or device. For this reason, I wanted to assess the benefits study

participants received from participating in a non- pharmaceutical study. This can help to show that clinical research can offer participants a wide range of benefits, and most often these benefits are not in the aim of the study. In a similar study conducted in the United Kingdom, study-related feedback provided to parents helped raise awareness of their child's health risks and influenced more than one-third of the parents, with either overweight or obese children, to seek further knowledge about improving their child's health (Falconer et al., 2014). The goal of my study was to assess similar changes such as if the parent/legal guardian became more aware of the child's health after participating in the initial two studies, and if this awareness influenced them to make changes in the child participants' lifestyles.

SPECIFIC AIMS

The study was set up to answer the following aims. Comparative data were used to assess changes made in the patients' life style from before follow-up results were received (during initial study visit) to after follow-up results were received.

Aim 1. To determine if study results were beneficial to the parents in recognizing their child's current health.

Hypotheses:

1.1 Receiving abnormal results will be associated with increased awareness of the child's health.

1.2 Child participants who received abnormal results will have had more doctor visits, as compared to child participants who received normal results.

Aim 2. To determine if study results influence the child to make changes to their diet or level of physical activity, as reported by the parent?

Hypotheses:

2.1 Parents of child participants who received abnormal results will have made changes to the child's diet, as compared to parents of child participants who received normal results.

2.2 The physical activity for children who received abnormal results will increase, as reported by parents, when compared to those who received normal results.

Aim 3. To determine if receiving abnormal or normal results is associated with parents' willingness to participate in future studies or to let their child participate in future studies.

Hypothesis:

3.1 Parents' willingness to participate in future research studies or have their child participate in future research studies will be associated with having received normal or abnormal results for their child.

SIGNIFICANCE

Clinical research is a vital component in advancing health care. These advances are largely due to those individuals who have volunteered in past studies regardless of the participant's quality of life, healthy or not. In 2004, it was noted that between five and six million people participated in some form of clinical research (Parkinson Pipeline Project, 2012). The National Institutes of Health (NIH) recognizes that volunteers are essential to research, and in order to continue progressing, the challenges of recruitment must be tackled. This includes bringing awareness about clinical research so the public will see it as the "social good that it is" (Bower et al, 2009).

Specifically, in reference to clinical trials involving child participants, recruitment is often more challenging when compared to the recruitment of adult participants. This may be the result of many factors including the fact that the NIH did not pass a policy requiring the inclusion of children in all of their human studies until 1998. Another factor may be due to parent's hesitancy to allow their children to participate for fear of their child being treated as a "guinea pig" or their concerns/anxiety regarding the primary motive behind researchers (Caldwell, Murphy, Butow & Craig 2004). These types of concerns provide researchers more incentive to document benefits associated with participating in research as it can help individuals recognize that although there are potential risks, potential benefits are an equally if not more important factor for study participants. In regards to this particular study, parents could have also potentially improved their awareness about their child's health. This could then have helped to provide positive influences for both the child and the parent/legal guardian, allowing them to make necessary lifestyle changes.

Another important note is that there are a number of individuals who have previously participated in research which are willing to participate a second and third time. This shows that in some way the participant felt rewarded or more encouraged after participating. Whether it was for a personal benefit and/or an altruistic benefit, they want to continue to provide researchers with their assistance. This is why the survey obtained information regarding the parent's willingness to participate in future studies, along with the willingness to allow their child to participate in future studies. This will help to show whether or not individuals are content with their experiences and therefore likely to participate again.

Lastly, this study assessed if participation in a clinical study helped play a role in the parent's increased awareness of their child's health. This improved awareness was not the primary aim in either of the two initial studies, but should be documented as an added benefit. I should note that this study does not in any way coerce individuals into participating, but rather bring them awareness about research and its potential benefits to allow them to consider participating.

MATERIALS AND METHODS

STUDY POPULATION

Potential participant's information was collected from both studies titled "Factors Associated with Being at Risk for Type 2 Diabetes among Mexican American and Mexican Children" (PI: Dr. Kimberly Fulda), and "Psychosocial and Physiological Predictors of Type 2 Diabetes Mellitus Risk among Children Aged 10-14" (PI: Nusrath Habiba). Only those subjects that were fluent in English and agreed to be contacted for future studies were contacted for this study. There were 182 contacts collected from the initial two studies, 33 from "Psychosocial and Physiological Predictors of Type 2 Diabetes Mellitus Risk among Children Aged 10-14" and 149 from "Factors Associated with Being at Risk for Type 2 Diabetes among Mexican American and Mexican Children". Study subjects (parents/legal guardians) included both male and female participants which were all at least 18 years or older but varied in age distribution. A one-time survey was administered over the phone and was completed by the parent/legal guardian of the child participant from the original studies. Participants were contacted as early as August 26, 2014, and phone calls were made up until October 20, 2014. If an answer was not obtained on the first attempt, participants were contacted again up to three times maximum before being removed from the contact list. A call log was used to tally the number of times each participant was contacted and to record any interaction. There was a preference to obtain the responses from the same parent/legal guardian that participated in either of the two initial studies, as their responses were the most ideal when comparing data. However, there was one exception where

another parent/legal guardian completed the follow-up survey. A total of 61 surveys in the follow-up study were collected with a total of 3 past participants declining. Reasons for declining varied and included ‘not being interested’ or ‘lack of availability’. These subjects were thanked and removed from the call list. Reasons for not obtaining all 182 surveys also varied but included 50 parent/legal guardians that did not answer, 26 phone lines that were disconnected, 11 people who answered and said it was the wrong number, 9 parents/legal guardians were interested and asked to be called back later but then never answered, and 8 parents/legal guardians did not speak English.

Table 1 Reasons past participants did not participate in follow up study

	Frequency (n)	Percent (%)
Did not answer	50	27.5
Disconnected phone line	26	14.3
Wrong number	11	6.0
Showed interest and said to call back but then were never reached	9	4.9
Did not speak English	8	4.4
Declined	3	1.6

SURVEY INSTRUMENT

The survey assessed changes made in the child's lifestyle since participating in the study and was reported by the parent/legal guardian. The survey consisted of 17 questions total and lasted approximately 15 minutes. Participants were not compensated for the time it took to complete the survey. The survey contained some of the same questions (seven total) from the initial two studies to serve for comparison purposes only. Re-used questions included in the survey pertained to the child's general health, diet, and physical activity regimen. New questions were included to aid in assessing exact changes made to the child's diet and physical activity since completing the initial study. These questions also helped in gathering information regarding how helpful the parent/legal guardian found the study results to be and if the results influenced the parents to schedule more office visits with the child's primary care physician. Lastly, a question about the parent's/legal guardian's willingness to participate in future studies along with their willingness to allow their child to participate in future studies was included in the survey. Table 2 shows a breakdown of the question used in the follow up survey (post).

Table 2 Survey Questions

Repeated Questions:
In general, how would you describe your child's health?
During the past week, how many days did you child exercise, play a sport, or participate in physical activity for at least 20 minutes that made him/her sweat and breathe hard?
During the past week, on how many days did all the family members who live in the household eat together?
I intend to make my child eat healthy and exercise regularly. (scaled response)
Making my child eat healthy and exercise regularly will reduce their risk of developing diabetes. (scaled response)
In the past 3 months, I have made my child eat a healthy diet and exercise regularly. (scaled response)
My child is not overweight, he or she is at the correct healthy weight compared to children I know. (scaled response)
New Questions:
Since you and your child participated in the study, how many times has your child visited a physician?
Did the follow up results you received from you child participating in the study influence the scheduling of any of the above visits?
Did you feel like the follow up results were helpful?
Since you and your child participated in the study have you made any changes to your child's diet? (Had the option to list changes)
Has your child made any changes to their physical activities? (Had the option to list changes)
On an average weekday, about how many times does your child use a computer for purposes other than school work?
On an average weekday, about how many times does your child watch TV, watch videos or play video games?
How likely would you participate in another study?
How likely would you let your child participate in another study?

Because participants were contacted via a telephone call, a telephone consent was deemed appropriate. A telephone script, approved by the Institutional Review Board (IRB), was read to each individual before administering the study. It concisely described the aims of the study, listed what would be expected of the participants, explained how confidentiality would be

maintained, and explicitly asked for the parent's/legal guardian's consent to participate. A waiver of written documentation was also obtained from the IRB before any participant was contacted. This waiver was approved because the study involved no more than minimal risk to the subject, and consent was asked verbally after the participant was given all of the relevant information.

The data collected directly from the participants were stored in a clearly labeled binder in a locked file cabinet located in the Texas Prevention Offices on the 7th floor of the EAD building. Eventually the data were entered using Statistical Package for the Social Sciences **(**SPSS) software and excel. Each participant received a unique identification number (UIN) in order to maintain confidentiality. The same UINs as those assigned in the initial studies were used as a way to maintain organization throughout the study. Also, in order to merge pre and post responses, SPSS required the same UINs. The cover letter was the only sheet which held information linking the participant's name with their assigned unique identification number (UIN). This cover letter was later separated from the survey and locked away in a file cabinet to avoid any breach of confidentiality. Data collected from the databases created for the existing, original studies (IRB # 2011-136 and IRB # 2012-151), were stored electronically and secured by a passcode.

DATA ANALYSIS

Aim 1. To determine if study results were beneficial to the parents in recognizing their child's current health.

Hypotheses:

1.1 Receiving abnormal results will be associated with increased awareness of the child's health.

Data were collect for the following questions:

1. In general, how would you describe your child's health? (Excellent, Very Good, Good, Fair and Poor)
2. Making my child eat healthy and exercise regularly will reduce their risk of developing diabetes. (Responses will include a scale ranging from 1 to 7, 1 being unlikely and 7 being likely.)
3. My child is not overweight, he or she is at the correct healthy weight compared to children I know. (Responses will include a scale ranging from 1 to 7, 1 being agree and 7 being disagree.

ANALYSIS FOR HYPOTHESIS 1.1

Responses from the initial study visit (pre) were compared to the responses collected with the follow-up survey (post). The questions and response options were the same. The parents/legal guardians had the option to rate their child as

having Excellent, Very Good, Good, Fair or Poor health. These response were dichotomized by pairing Poor, Fair, Good into one variable (reference) and Very Good/ Excellent into another. Logistic Regression was utilized to examine the association between study results (independent variable: normal/abnormal results) and reported health of the child (dependent variable: 'poor,fair,good'/ 'very good,excellent'). Additionally, the odds ratios and 95% confidence intervals were calculated. Multiple logistic regression was used to control for potential confounders such as child gender, child age, and child race/ethnicity. Results were considered statistically significant at an alpha value less than or equal to 0.05.

For Questions 2 and 3, means, standard deviations, and medians were calculated. A related-samples Wilcoxon Signed Rank Test was performed to compare the median values between the pre and post responses for the normal and abnormal subgroups. Results were considered statistically significant at an alpha less than or equal to 0.05.

1.1 Child participants who received abnormal results will have had more doctor visits, as compared to child participants who received normal results.

Data were collected for the following questions:

4. Since the study, how many times has your child visited a physician? (open ended response)

5. Did the follow up results influence the scheduling of any of the above visits?

ANALYSIS FOR HYPOTHESIS 1.2

The median number of office visits was compared between children who received normal and abnormal results using a nonparametric Mann-Whitney Test. Results were considered statistically significant at an alpha less than or equal to 0.05. A descriptive analysis of how receiving the results influenced scheduling the visits was utilized. The response options included 'Yes', 'No' and 'Don't Know'.

Aim 2. To determine if study results influence the child to make changes to their diet or level of physical activity, as reported by the parent?

Hypothesis:

2.1 Parents of child participants who received abnormal results will have made changes to the child's diet, as compared to parents of child participants who received normal results.

Data were collect for the following questions:

6. I intend to make my child eat healthy and exercise regularly. (Responses will include a scale ranging from 1 to 7, 1 being unlikely and 7 being likely.)

7. In the past 3 months, I have made my child eat a healthy diet and exercise regularly. (Responses will include a scale ranging from 1 to 7, 1 being true and 7 being false.)

ANALYSIS FOR HYPOTHESIS 2.1

Responses from the initial study visit (pre) were compared to the responses collected with the follow up survey (post). The questions and response options were the same. A related-samples Wilcoxon Signed Rank Test was performed to compare the median values between the pre and post responses for the normal and abnormal subgroups. Results were considered statistically significant at an alpha less than or equal to 0.05.

2.2 The physical activity for children who received abnormal results will increase, as reported by parents, when compared to those who received normal results.

Data were collect for the following questions:

8. During the past week, how many days did your child exercise, play a sport, or participate in physical activity for at least 20 min that made him/her sweat and breathe hard?
9. On an average weekday, about how much time does your child use a computer for purposes other than schoolwork?
10. On an average weekday, about how many times does your child usually watch TV, watch videos or play video games?

ANALYSIS FOR HYPOTHESIS 2.2

For question 8, responses from the initial study visit (pre) were compared to the responses collected from the follow up survey (post). The questions and response options were the same. A related-samples Wilcoxon Signed Rank Test was performed to compare the median values between the pre and post responses for the normal and abnormal subgroups. Results were considered statistically significant at an alpha less than or equal to 0.05.

Due to a mistake found in the follow-up survey, the pre/post responses to questions 9 and 10 could not be compared. Only descriptive measures for the total sample including mean, standard deviation, and median were calculated.

Aim 3. To determine if receiving abnormal or normal results is associated with parents' wiliness to participate in future studies or to let their child participate in future studies.

Hypothesis:

3.1 Parents' willingness to participate in future research studies or have their child participate in future research studies will be associated with having received normal or abnormal results for their child.

Non comparative data were collected from the following two questions:

11. Would you participate in another research study?
12. Would you let your child participate in another research study?

ANALYSIS FOR HYPOTHESIS 3.1

A Fischer's Exact Test was utilized to examine the association between study results (independent variable: normal/abnormal results) and willingness to participate in future studies (dependent variable: yes/no). Parents/legal guardians were asked to rank their willingness on a scale of 1-7, 1 being 'unlikely' and 7 being 'likely'. These responses were then dichotomized by renaming 1-4 as 'no' and 5-7 as 'yes'. Results were considered statistically significant at p-value less than or equal to 0.05.

RESULTS

SAMPLE OVERVIEW

Out of the 61 completed surveys, 11 (18%) came from parents of children who received all 'normal' results and 50 (82%) from those who received at least one 'abnormal' results (Table 3).

Table 3 Frequency Of Participants Who Received Normal Results Vs. Abnormal Results

	Frequency (n)	Percent
Normal	11	18.0
Abnormal	50	82.0
Total	61	100.0

The children varied demographically for which some of these factors were later controlled for during analysis. Depicted below are distributions regarding childs race, child's ethnicity and child's sex. Of the 61 children, whose parents completed the post survey, 28 (45.9%) were male and 33 (54.1%) were female. Additionally, 19 (31.1%) reported to be of Non-Hispanic/Latino origin and 42 (68.9%) reported to be of Hispanic/Lation origin. Lastly, the children ranged from 10-14 years at the time of the initial study, with an average of 11.95 years.

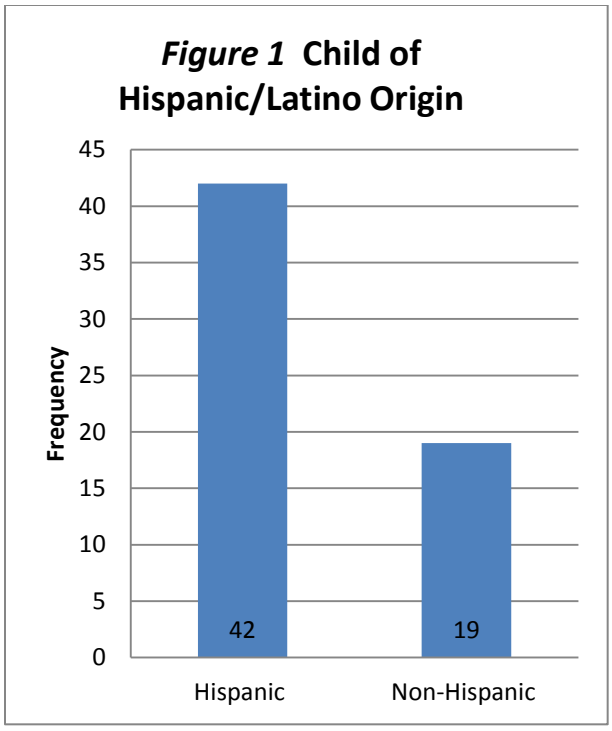


Figure 1 Child of Hispanic/Latino Origin
Frequency
45
40
35
30
25
20
15
10
5
0
42
19
Hispanic
Non-Hispanic

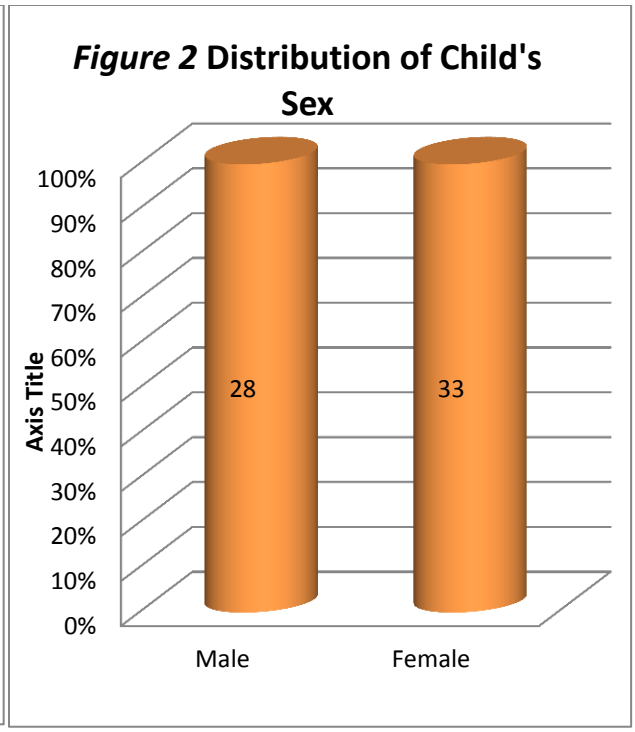


Figure 2 Distribution of Child's Sex
Axis Title
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
28
33
Male
Female

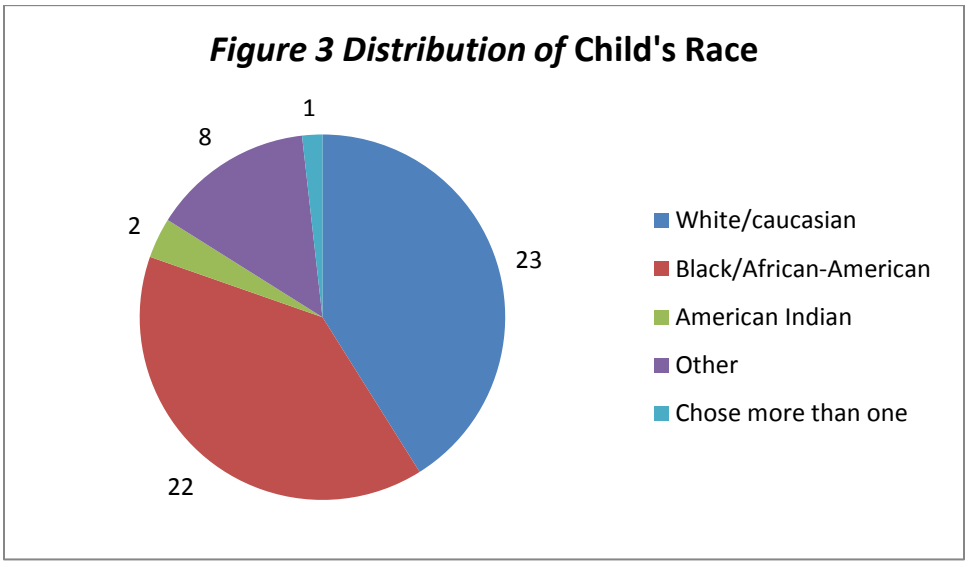
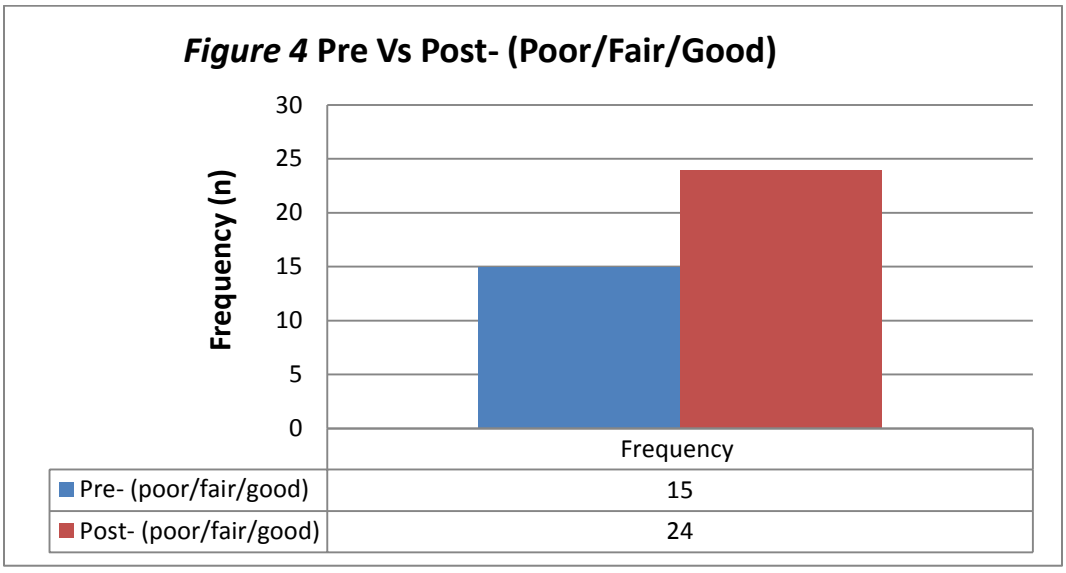


Figure 3 Distribution of Child's Race
1
8
2
23
22
White/caucasian
Black/African-American
American Indian
Other
Chose more than one

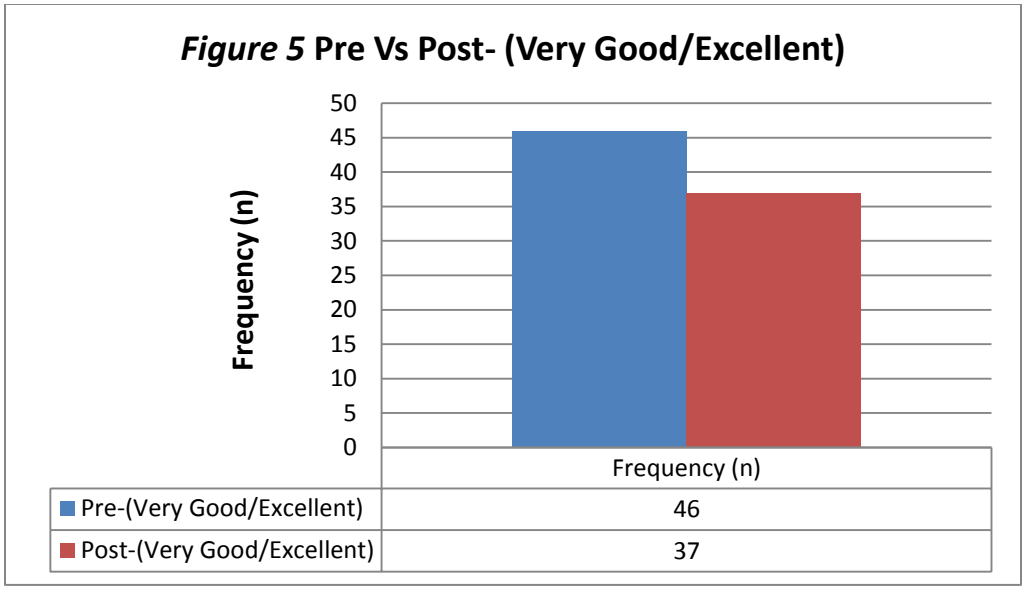
Specific Aim 1: To determine if study results were beneficial to the parents in recognizing their child's current health.

Hypothesis1.1 Receiving abnormal results will be associated with increased awareness of the child's health.

For the following question, "In general, how would you describe your child's health?", there were a total of 15 (24.6%) parents/legal guardians that rated their child as having 'poor/fair/good' health during the initial study (pre) as compared to 24 (39.3%) parents/legal guardians who rated their child as having 'poor/fair/good' health in the follow up study (post). These values are depicted in Figure 4.



When comparing the pre and post responses, there was a reported decrease in the number of parents/legal guardians who rated their child as having 'Very Good/ Excellent' health. The frequency fell from 46 (75.4%) in the initial study to 37 (60.1%) in the follow up study. This difference is represented in Figure 5.



Logistic regression was utilized to examine the association between received study results (independent variable: abnormal/normal) and reported health of child (outcome variable) (Table 4). Both 'normal' and 'poor/fair/good' were used as the reference group. The abnormal group had a 37% less odds of predicting 'Very Good/Excellent' health when compared to the normal group (OR:0.629; 95% CI: 0.144-2.758).

Table 4 Changes In Parent's Perception Of Their Child's General Health

	Simple Logistic Regression			Multiple Logistic Regression		
	OR	**95% CI**	**p**	**OR**	**95% CI**	**p**
Results						
Abnormal	0.629	0.144-2.758	0.539	0.481	0.092-2.519	0.386
Normal	---	---	---	---	---	---
Pre Health						
Poor / Fair / Good						
Very Good / Excellent	2.913	0.862-9.849	0.085	2.844	0.816-9.904	0.101
Age						
10-14 years				0.679	.596-1.401	0.680
Gender						
Male				2.254	0.701-7.248	0.173
Female				---	---	---
Race/Ethnicity						
Hispanic				0.679	0.198-2.322	0.537
Non- Hispanic				---	---	---

***(---) This variable was used as a reference/ control**
***(95% CI)- 95% Confidence Interval**
***(p)=P-value**
***OR-Odds Ratio**
***CI- Confidence Interval**

Table 4 also shows that those who picked 'Very good/Excellent' in the initial study (pre) had three times the odds of picking 'Very good/Excellent' in the follow up study (post) (OR:

2.913; 95% CI: 0.862-9.849). Multiple logistic regression was used to control for potential confounders such as child gender, child age and child race/ethnicity (Hispanic or Non-Hispanic). Again, according to the calculated odds ratio and confidence interval, there was a non-significant negative association between those with abnormal/normal results and "Very Good/ Excellent' post responses (OR: 0.481, 95% CI: 0.092-2.519). It was interesting to note that when controlling for gender, parents/legal guardians of male children had 2 times the odds of reporting a 'Very Good/Excellent' health rating as compared to the parents/legal guardians of female children.

Descriptive measures for the following survey question, "Making my child eat healthy and exercise regularly will reduce their risk of developing diabetes" were calculated using SPSS, and values were recorded in Table 5. The median measured for all categories (abnormal/normal and pre/post) was recorded at 7.0. Due to skewed data, medians, instead of means, were used for comparison purposes. This is preferred when skewed data are collected as outliers can greatly influence the mean value making it a bad measure for central tendency. According to the calculated p-values post responses did not show a statistically significant difference for either group (normal: p=0.340, abnormal: p=0.869).

Table 5 Changes In Parent's Perceptions Regarding Diet and Exercise And Their Correlation With Type 2 Diabetes

	Mean	SD	Median	p
Normal :				
Pre	6.0	1.897	7.0	0.340
Post	6.73	.647	7.0	
Abnormal:				
Pre	6.74	.751	7.0	0.869
Post	6.70	.751	7.0	

*SD=Standard deviation
*p= P-value calculated using a Wilcoxon Signed Rank Test

Descriptive measures for the following survey question, "My child is not overweight, he or she is at the correct healthy weight compared to children I know", were calculated using SPSS, and values were recorded in Table 6. The median for the pre response in both normal and abnormal populations was calculated at 5.0. The median for the post response in both normal and abnormal populations was calculated at 7.0. Differences in pre and post values for the normal

subgroup were not significant (p=0.136). Comparatively, the abnormal subgroup shows a statistically significant change in responses (p=0.021).

Table 6 Changes for Parent's Perception Regarding Their Child Not Being Overweight

	Mean	SD	Median	p
Normal :				
Pre	5.182	1.328	5.0	0.136
Post	6.180	1.471	7.0	
Abnormal:				
Pre	3.832	2.168	5.0	0.021*
Post	5.18	2.362	7.0	

*(*)= significant (p< 0.05)
*SD=Standard deviation
*p= P-value: calculated using a 'Wilcoxon Signed Rank Test' (comparison of medians)

Hypothesis 1.2 Child participants who received abnormal results will have had more doctor visits, as compared to child participants who received normal results.

Responses to the following question, "Since the study, how many times has your child visited a physician?", were collected during the follow-up study (post), only. The goal was to determine if having received normal or abnormal study results influenced the number of times

a child visited a physician. The response distribution for the total population ranged from 0 to 7, with 1 visit being the most commonly reported value.

Table 7 shows the calculated descriptive measures including mean, standard deviation and median. A Mann-Whitney test was performed to assess an association between study results (independent variable: Normal/Abnormal) and number of visits (dependent variable). Although the difference is not statistically significant, the abnormal populations reported a slightly higher number (median=1.5 visits) as compared with the normal population (median=1.0) (p=0.598).

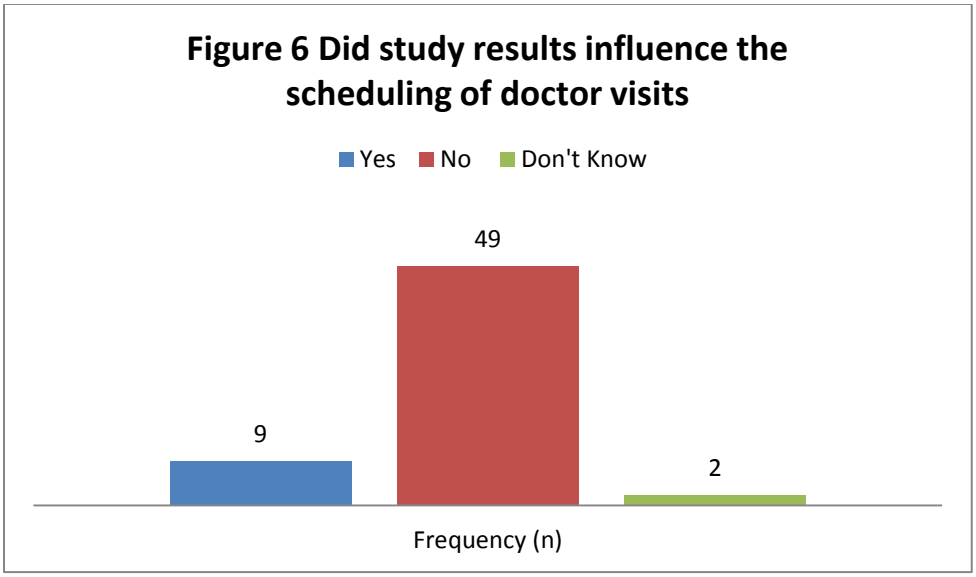
Table 7 Compared Child Visits for Normal and Abnormal Populations

	Mean	SD	Median	p
Number of Visits Total	1.672	1.411	1.000	0.598
Normal	1.545	1.440	1.000	
Abnormal	1.700	1.418	1.500	

*SD=Standard Deviation
*p=P-value

Secondly, we wanted to assess if received study results influenced the scheduling of any reported doctor visits. A total of 49 (80.3%) parents/legal guardians reported that study results

did not play a role in scheduling the doctor visits, 9 (14.8%) parents/legal guardians reported that the study results did play a role in scheduling doctor visits, and 2 (3.2%) parents/legal guardians were unsure if the study results played a role or not. These values are depicted below in Figure 6.



Aim 2. To determine if study results influence the child to make changes to their diet or level of physical activity, as reported by the parent?

Hypothesis 2.1: Parents of child participants who received abnormal results will have made changes to the child's diet, as compared to parents of child participants who received normal results.

For the following survey question, "I intend to make my child eat healthy and exercise regularly", the mean, standard deviation and median values were calculated using SPSS and the values recorded Table 8. Due to the skewed data, comparison of medians was preferred as they most accurately measured central tendency. At the time of the initial study, the average median for the 61 participants was calculated at 5. 967, compared to 6.070 in the follow-up study. When these values were calculated using abnormal/ normal subgroups, the median for both increased from 6.0 (pre) to 7.0 (post) (p=0.510, 0.121, respectively).

Table 8 Parent's/Legal Guardian's intent to make their child eat healthy and exercise regularly

	Mean	SD	Median	p
Total				
Pre	5.967	1.140	6.000	
Post	6.070	1.580	7.000	
Abnormal				
Pre	6.020	1.134	6.000	0.510
Post	6.000	1.690	7.000	
Normal				
Pre	5.727	1.191	6.000	0.121
Post	6.360	0.855	7.000	

**SD=standard deviation*
**P=p-value: calculated using a Wilcoxon Signed Rank Test (comparing medians)*
**-Statistically significant (p<0.05)*

For the following survey question, “In the past 3 months, I have made my child eat a healthy diet and exercise regularly”, descriptive measures were calculated including mean, standard deviation and median values and recorded below in Table 9. Due to the skewed data, comparison of medians was preferred as they most accurately measured central tendency. At the time of the initial study, the average median for the 61 participants was calculated to be 4.230. This can be compared to the follow-up study, which had an increased calculated median of 5.920. Median values for the normal and abnormal subgroups increased from 6.0 (pre) to 7.0 (post). A related-samples Wilcoxon Signed Rank Test was performed to assess if these changes had a statistically significant difference. Both samples (abnormal/normal) proved to be statistically significant for their change in post responses (pre vs post) (abnormal: $p=0.000$, normal: $p=0.024$). These values can be found below in Table 9.

Table 9 Parents/Legal Guardians have made their child eat a healthy diet and exercise regularly in the past 3 months

	Mean	SD	Median	p
Total				
Pre	4.230	1.979	4.0	
Post	5.920	1.810	7.0	
Abnormal				
Pre	4.280	2.051	4.500	0.000*
Post	6.000	1.690	7.000	
Normal				
Pre	4.000	1.673	4.000	0.024*
Post	6.090	1.373	7.000	

**SD=standard deviation*
**P=p-value: calculated using a Wilcoxon Signed Rank Test (comparing medians)*
**(*)-Statistically significant (p<0.05)*

Hypothesis 2.2: The physical activity for children who received abnormal results will increase, as reported by parents, when compared to those who received normal results.

2.1 The physical activity for children who received abnormal results will increase, as reported by parents, when compared to those who received normal results.

For the following survey question, "During the past week, how many days did your child exercise, play a sport, or participate in physical activity for at least 20 min that made

him/her sweat and breathe hard?", descriptive measures including mean, standard deviation and median were calculated and recorded in Table 10. Due to the skewed data, medians were compared as they most accurately measured central tendency. At the time of the initial study (pre), the median for all 61 participants was calculated to be 5.0. In the follow-up study (post) the median was unchanged (5.0). These values were then separated into the abnormal/normal subgroups. The median for the abnormal subgroup was calculated to be 5.0 for both pre and post. On the other hand, the normal population was 3.0 (pre) and increased to 5.0 (post). A Mann-Whitney test was performed to assess if these changes had any statistical significance. Both samples (abnormal/normal) proved to have a no statistically significant differences (abnormal: $p=0.702$, normal: $p=0.083$).

Table 10 How many days a week does the child exercise for at least 20 minutes

	Mean	SD	Median	p
Total				
Pre	4.273	2.1034	5.000	
Post	4.545	1.942	5.000	
Abnormal				
Pre	4.522	2.074	5.000	0.702
Post	4.478	1.9176	5.000	
Normal				
Pre	3.000	1.871	3.000	0.083
Post	4.884	2.1473	5.000	

**SD=standard deviation*
**P=p-value: calculated using a Wilcoxon Signed Rank Test (comparing medians)*
**-Statistically significant (p<0.05)*

Due to a mistake found in the follow-up survey, the responses to the following question "On an average weekday, about how much time does your child use a computer for purposes other than schoolwork" could not be compared using a pre and post response. In the initial study (pre) parents/legal guardians were asked to provide the average number of hours per day the child uses the computer for purposes other than school work. As for the follow-up survey (post), parents/legal guardians were asked to provide the number of days per week the child uses

the computer for purposes other than school work. Descriptive measures including mean, standard deviation and median were calculated and values depicted in Table 11. The average median for the overall population was calculated to be 1days a week. When comparing median values between abnormal and normal subgroups, both populations had a calculated value of 2 days a week (Table 11). This shows that there was no difference among the two populations.

Table 11 Days the child uses computer for purposes other than school work

	Mean	SD	Median
Total	2.450	2.464	1.000
Abnormal	4.220	1.385	2.000
Normal	3.900	1.257	2.000

**SD=standard deviation*

Due to a mistake found in the follow-up survey, the responses to the following question "On an average weekday, about how many times does your child usually watch TV, watch videos or play video games?" could not be compared using a pre and post sample. In the initial study (pre) parents/legal guardians were asked to provide the average number of hours per day the child watches TV, watches videos or plays video games. As for the follow-up survey (post), parents/legal guardians were asked to provide the number of days per week the child

watches TV, watches videos or plays video games. Descriptive measures including mean, standard deviation and median were calculated and values depicted in Table 12. The average median for the overall population was calculated to be 3 days a week.

When comparing median values for the abnormal and normal subgroups, both populations had a calculated value of 2 days a week (Table 12). This shows that there was no difference among the two populations.

Table 12 Days the child uses watches TV, watches videos or plays video games

	Mean	SD	Median
Total	3.090	1.640	3.000
Abnormal	3.46	1.764	4.000
Normal	3.39	1.735	4.000

**SD=standard deviation*

Aim 3. To determine if receiving abnormal or normal results is associated with parents' willingness to participate in future studies or to let their child participate in future studies.

Hypothesis 3.1: Parents' willingness to participate in future research studies or have their child participate in future research studies will be associated with having received normal or abnormal results for their child.

Due to the small sample size and lack of normality in responses, a Fischer's Exact Test was utilized to examine the association between study results (independent variable: normal/abnormal results) and willingness to participate in future studies (dependent variable). There were a total of 8 (16%) parents/legal guardians in the abnormal population which were not willing to participate in future studies nor let their child participate in future studies. On the other hand, none (0%) of the parents/legal guardians in the normal population reported that they were not willing to participate in futures studies as well as not let their child participate in future studies. There were 11 (100%) parents/legal guardians in the normal population which were willing to participate in future studies as well as let their child participate in future studies. Additionally, 42 (84.0%) of the parents in the abnormal population reported that they would be likely to participate in future studies as well as let their child participate in future studies. These values are depicted in the following two tables, 13 and 14.

Table 13 Parent's Willingness To Participate In Future Studies

	Normal (n)	**%**	**Abnormal (n)**	**%**	p
	Frequency		Frequency		
Yes	11	100.0%	42	84.0%	0.330
No	0	0.0%	8	16.0%	

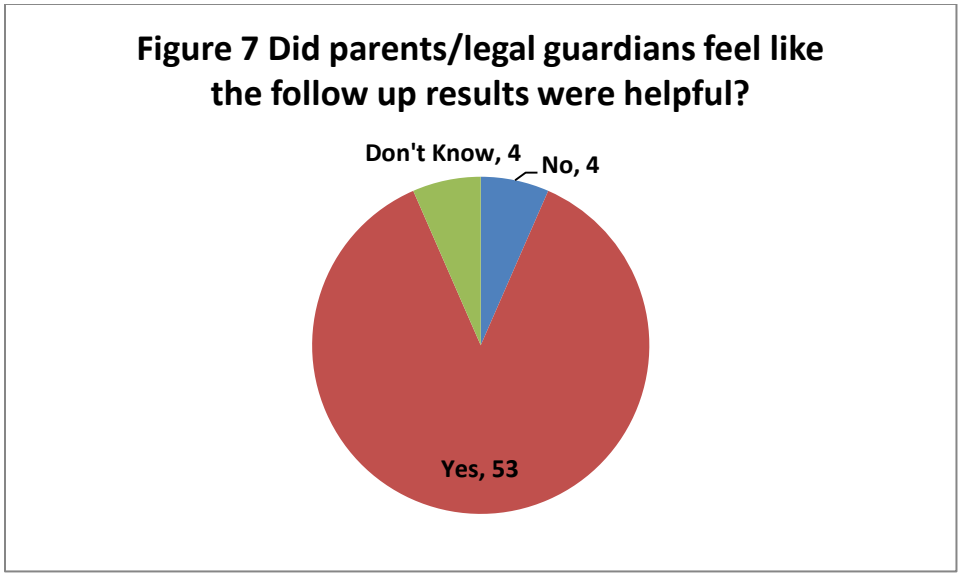
**P=p-value: calculated using Fisher's Exact Test*
**-Statistically significant (p<0.05)*
**(n)- Frequency*

Table 14 Parent's Willingness To Let Their Child Participate In Future Studies

	Normal (n)	**%**	**Abnormal (n)**	**%**	p
	Frequency		Frequency		
Yes	11	100.0%	42	84.0%	0.330
No	0	0.0%	8	16.0%	

**P=p-value: calculated using Fisher's Exact Test*
**-Statistically significant (p<0.05)*
**(n)- Frequency*

In addition to the above results, results regarding the new questions are listed below. Parents/ legal guardians were asked "If they felt study results were helpful?". The distribution of responses is depicted below in Figure 7. A total of 53 (86.9%) parents felt that results were beneficial, while 4 (6.6%) felt that they were not.



To further assess any changes made since the initial study, the parents/legal guardians were explicitly asked if their child made any changes to either their diet or physical activities. They were further asked to provide examples of such changes. A total of 34 (55.7%) parents/legal guardians reported a change in the child's diet. Additionally, 43 (70.5%) parents/legal guardians reported a change in the child's physical activities. The frequencies for those that answered yes/no are depicted in Table 15.

Table 15 Were changes made to the child's diet or physical activities?				
	Diet		Physical Activites	
	Frequency (n)	Percent (%)	Frequency (n)	Percent (%)
Yes	34	55.7	43	70.5
No	27	44.3	18	29.5

As for reported changes, both diet and physical activities varied. All 34 participants that changed their diet said they attempted to eat healthier. Of these 34, 10 reported that they included more veggies/fruits in their diet, 8 reported the child ate smaller portions, and 14 reported to cut back on fatty foods. Those who reported cutting back on fatty foods had a range of foods they gave as examples including red meat, fast food, instant meals, bread, whole milk and sodas. These values are listed in Table 17.

For physical activities, 43 people said their child made a change in their normal everyday regimen. The most common change was enrolling in an extracurricular activity at school, which was reported by 30 parents/legal guardians. This included, but was not limited to, ROTC, basketball, football, tennis and dance. There were 11 parents/legal guardians that reported their child exercised more on a regular basis whether it was walking on a treadmill or practicing a sport. These values are listed in Table 16.

Table 16 Changes made to diet and physical activities		
	Frequency (n)	Percent (%)
Diet		
Add more fruits/veggies	10	16.4
Smaller portions	8	13.1
Cut back on fatty foods	11	18.0
Exercise		
Exercise more	11	18.0
Involved in an extracurricular activity	30	49.2

Lastly, due to open ended questions, there were a few reports to make mention of. A total of six parents/legal guardians reported their child had gained weight after completing the study. Two parents reported that the study definitely played a role in the child's decision to lose weight and both parents/legal guardians thanked UNTHSC for these positive changes. One parent reported that she learned a lot about Type 2 Diabetes while participating in the study and wanted to thank both the child's pediatrician, Dr. Habiba, for her recommendations and UNTHSC. There was one parent/legal guardian that reported her child receiving a certificate from the school recognizing the child's attempt to exercise regularly

DISCUSSION

The literature regarding benefits associated with clinical research mainly has to do with those assessed in the primary aim of the study. These reported benefits include access to new and improved treatments, an increased survival advantage, and access to free medical care (Caldwell, 2004; Davis, 1985; Goal, 2012 & Knowler, 2002). There is little literature describing unexpected benefits, especially improved awareness of health or even lifestyle changes (Espinoza, 2014; Falconer 2014 & Morin, 2009). However, in this study more than half of the parents/legal guardians reported that their child changed some aspect of their lifestyle upon completion of the initial study. Whether it was diet (55.7%) or physical activities (70.4%), children seemed to be on the right track for living a healthier lifestyle. These changes were not in the aims of the primary study, nor did researchers in the primary study recommend making such changes after completing the initial study. Parents/legal guardians were also more likely to say their child was not overweight, a trend seen in both the abnormal and normal populations. When asked to rate if parents/legal guardians felt their child was 'not overweight' on a scale of 1-7 (1 being 'disagree' and 7 being 'agree'), parents changed from a median of 5.0 (pre) to 7.0 (post). These values proved to be statistically significant for the abnormal population ($p= 0.021$). While the normal population did not show any statistical significance, it is evident that the parent/legal guardian felt more confident that their child was not overweight at the time of the follow-up study.

In a similar study which provided feedback results to parents classifying their child as being overweight or not, researchers documented that more than one third of the parents who received 'overweight' results tried to seek further information regarding this issue. Unfortunately, they also reported that these results did not translate into any lifestyle changes (Falconer et al., 2014). Comparatively, this follow-up study showed that there was not a significant difference in the number of physician visits scheduled for the children who received abnormal results compared to those with normal results. Although, the abnormal population did show a slight increase with 1.5 median visits as compared to 1.0 median visits in the normal populations. Additionally, only 9 parents/legal guardians reported that the study results played a role in scheduling a doctor's visit concluding that this factor may or may not have played an influential role in seeking further information.

Additionally, the willingness of the previous participants to participate in future studies was assessed. Previous follow-up studies have recorded participants' willingness to participate in future studies. It seems that majority of individuals are happy with their experiences in clinical studies and thus more likely to participate again (Falconer et al., 2014). This follow-up study proved to be consistent with such findings with 84% of parents/legal guardians reporting that they were likely to participate in a future studies as well as let their child participate in future studies. Secondly, 86.8% felt that the study results received in the initial study were helpful. Based on these results, the majority of the participants had a positive experience with the initial study and thus more likely to participate again.

Lastly, the most significant finding was that parents/legal guardians reported they made increasing attempts to have their child eat healthy and exercise regularly. While this finding cannot be completely accounted for in regards to participating in the initial study, participation may have been a factor in such decisions.

Overall, it appears as though a majority of the parents/legal guardians improved their awareness of their child's health, which led them to make more positive decisions in the child's diet and exercise regimen. Furthermore, more than half of the children made positive changes in their diet or exercise regimen including eating healthier, cutting out fatty foods, enrolling in an extracurricular activity and exercising more often.

LIMITATIONS

In any clinical study there is room for possible bias. When it comes to data collection and analysis, bias can result in an incorrect assessment of the study hypotheses. Specifically, in this study a self-reported survey was provided to participants to aid in describing their/their child's experiences since completing the initial study. The survey used involved a few closed-type questions which provided the participant with limited answer choices. Although this helps to simplify the analysis of the data, it does pose a potential limitation. Participants were restricted to answering questions in a more simplistic manner and thus could not fully elaborate on some responses. Therefore, it was difficult to completely assess the participants' improvements due to the simplicity of the answers obtained.

Another limitation was recall bias. This type of bias is also commonly seen in studies involving surveys. In this study, parents were asked about changes made in their child's diet and physical activity. Parents of children who received abnormal results may remember changes more so than the parents of children who received normal results. Besides recall bias, there was a single issue where the parent/legal guardian surveyed was not the same parent/legal guardian surveyed in the initial study. This can raise questions regarding the comparison responses for that particular subject. Additionally, two questions were misworded in the follow-up survey which made it impossible to compare responses obtained in the follow-up survey to those responses in the initial study (pre).

Aside from the above limitations, it is important to note that only the past participants who agreed to be contacted for future studies were re-contacted and asked to participate in the follow-up survey. This may have had an influence on the results collected for the two questions regarding willingness to participate in future studies.

Lastly, analysis was carried out using a small sample size. Due to the short length of the internship and a large number of individuals who were not reached, only 61 surveys were collected. With small sample sizes Power (1-B) can be greatly affected. Power is the ability to statistically detect a difference when the difference truly exists. Therefore, there may be evidence of a difference detected but the sample size is too small to show the difference has any statistical significance. In comparison, a large sample size is more likely to produce more precise results with narrower confidence intervals making it easier to detect a statistical significance. Another issue when working with a small sample size is difficulty controlling for confounding variables (covariates).

CONCLUSION

The purpose of this research was to assess potential benefits study participants received after participating in a previous clinical study at the University of North Texas Health Science Center. These benefits included parents/legal guardians increased awareness of their child's health and positive changes made in the child's lifestyle. In the previous studies, participants received results classifying their children as having either normal or abnormal lab values. This factor was later assessed to determine if it had any association with the child's outcomes.

Although there were only a few variables proving to be statistically significant, there were many positive changes reported by the parents. More than 50% of those contacted reported that their child made a change in either their diet or physical activities since completing the study. Furthermore, it seemed that parents/legal guardian were more aware of their child's health and more inclined to make their child eat healthier and exercise more often. Lastly, 84% of the parents/legal guardians that participated in the follow up survey reported that they were likely to participate as well as let their child participate in future studies.

The advancements made in health care thus far would not be possible without the research and most importantly the participants who have already volunteered. Knowledge used in public health along with medications and intervention programs implemented in clinical settings are often taken for granted but were all made possible by research. In order to continue this path of improvement, it is important to tackle issues of problematic recruitment and

encourage more individuals to consider participating. By adding to the literature that accounts for benefits associated with participating in clinical studies, I hope to provide individuals with a different perspective of clinical researcher. Individuals, especially parents, should be informed that sometimes the outcome of participating in a clinical study is learning something about yourself or even your child. This type of benefit may further influence participants to make positive changes in their lifestyles which can help to improve their health even after completing the study.

CHAPTER III

INTERNSHIP EXPERIENCE

For my internship, I was paired with Dr. Kimberly Fulda, Associate Professor in the Department of Family Medicine and the Associate Director of the Primary Care Research Center. While working for Dr. Fulda, I was responsible for a number of daily activities associated with the various clinical studies being developed during this time period. My goal was to learn in depth the process of carrying out a clinical study and to engage in all aspects of clinical research. I was also able to attend an Institutional Review Board (IRB) meeting as a way to familiarize myself with the process involved in approving potential clinical studies. I worked closely with Michelle Lee, a research coordinator, preparing necessary paperwork and collecting data for studies, including "UNTHSC Development and Validation of Clinically Practical Patient Assessment: Engagement, Literacy and Adherence (P-ELA)" and "Environmental Sampling and Processing of Samples for the Presumptive Identification of *Clostridium difficile* Isolates". Below I have detailed my experience with these studies.

1.) Health Literacy

Dr. Fulda received IRB approval for this protocol which went into effect June 27, 2014 and closes June 27, 2015. The ultimate goal of this study is to develop a brief Patient-ELA tool that physicians can use in a clinical setting to aid in interacting with patients at an individualized

level. This tool will be developed after surveying patients using seven previously validated tools designed to assess health literacy, patient adherence and engagement preferences. Researchers will then pull a subset of the items from the previous surveys as a way of comprising the same information using a single tool. Potentially this will aid in improving patient outcomes by improving patient-physician shared-decision making and increasing effective health education interactions.

There were a total of 200 participants surveyed, 100 in the Kentucky area and 100 here at UNTHSC's Patient Care Center. The first step was to organize the necessary materials need ed to complete recruitment. This consisted of making a binder for each researcher assistant that was trained in the recruitment process. The binder included all seven surveys with necessary directions and response cards, the protocol, recruitment scripts, potential participant tracking sheets, copy of informed consent, and disbursement log. This binder was clearly labeled and organized in a way that would facilitate recruiting participants along with tracking the necessary information. The next step was to create folders for each participant involved. This required purchasing 100 folders and labeling them with correct UINs. UINs started with TX-101 and ended with TX-200. Each folder was equipped with a checklist that aided the research assistant in making sure all necessary items were collected, an informed consent, and all seven surveys. We were also required to purchase 100 target gift cards as a ten dollar compensation was provided to each participant upon completion of the study. A log of each gift card was kept in the TPI offices along with a log detailing when the gift card was checked in/out and by which research assistant. The next step was to receive training on how to administer the surveys and

how to properly present the informed consent. The informed consent is a vital process in which research personnel are required to present to the potential participants a clear understanding of what the study entails, including the purpose of the study, study procedures, potential risk and discomforts associated with the study, contact information for the principal investigator, associated benefits, compensation and ways researchers were to maintain confidentiality. It was important to make each participant aware that their decision to participate was completely voluntary and that they were able to leave the study at any time without penalty. Once each participant had sufficient time to review this and decided if they wanted to participate, they were required to sign and date each individual page of the informed consent. A copy of the informed consent was made and was given to each participant after completing the study. As a way of maintaining confidentiality, surveys were administered orally in a private room, either the patient room in between the time the patient had their vitals checked and when the doctor was present, or a designated research room. Files for each participant were brought back to the TPI offices and kept in a locked file cabinet. They were later accessed for data entry. Double data entry was required, and results were sent to the Kentucky site for further analysis.

2.) Clostridium Difficile

The purpose of this study is to ultimately understand the prevalence of *Clostridium Difficile* in certain health care facilities. Specifically, in the Dallas/Fort Worth area there has been a reported increase in acute patient discharges, 6.99/1,000 to 9.51/1,000, from 2010 till now. This project was designed to do two things: determine the prevalence of C. Diff in both rural and urban clinics, hospitals and nursing homes in the nearby areas and secondly to educate the staff of these

facilities on the best practices regarding cleaning techniques and the importance of personal hygiene.

This project recruited a total of 33 clinics, hospitals and nursing homes in both rural and urban settings. Each facility was contacted and agreed to participate in three pre and three post environmental screen processes with a total of six site visits. Each environmental collection consisted of swabbing specific areas including light switches, door knobs, window blind wands and curtains, restroom commodes, sink handles, keyboards and bedrails. Our first job was to contact all of the facilities and set up pre and post dates for the swabbing. Once this was completed we made folders for each site. The folders were equipped with contact information and address for the facility, a pre and post survey, a checklist for the research assistant performing the swab, 6 sheets to record UINs for each individual swab and a 'How-to' regarding correct techniques for environmental sampling. We were also required to set up the tools necessary to complete the swab. This included a box containing a lab coat, safety glasses, eight sterile gloves, eight cotton swabs and twirl 'em bags (including one for a negative control), saline solution and a hazardous waste bag. Each person that was involved with collecting samples was trained by Dr. Joon Lee, Assistant Professor in Environmental and Occupational Health Sciences. Once training was complete, we started collecting samples. After the first three samples were collected, the facilities had the option to participate in a C. Diff education session. Another three samples were collected post education session to see if there were any changes in prevalence. Propagation and identification of *Clostridium difficile* isolates were done here on the UNTHSC campus and double data entry was performed for further analysis.

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