Available Online at http://www.bjbmr.org

ISSN:2456-9739

BRITISH JOURNAL OF BIO-MEDICAL RESEARCH

Cross Ref DOI: https://doi.org/10.24942/bjbmr.2018.337 Volume 02, Issue 05, Sept -October 2018

Research Article

An Evaluation of Variations In Health Knowledge And Régimes After Participating In Clinical Study

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ARTICLE INFO

Article History:
Received on 06th Sept 2018
Peer Reviewed on 26th Sept 2018
Revised on 14th October 2018
Published on 28th October 2018

Keywords:
Clinical trials, Engagement, Recruitment, Retention, Patient-centeredness, Trial design

ABSTRACT

Aim: 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.

Method: 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: study outcome 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.

Conclusion: 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.

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INTRODUCTION

There is an overarching assumption that medical research, in general, is a good thing. Even those who don't subscribe to this arguably simplistic view would hold that medical research is absolutely necessary. This situation is made complex by a widespread expectation that science and technology are expected to be capable of curing all conditions. Society and the medical community have come to the conclusion that research on humans is both necessary and desirable. This poses urgent questions, however, when we consider the poor quality and poor outcomes of most clinical trials and basic science experiments [1-7] As clinical trials and sentinel data expand in number and location, the necessity and relevance of research's worth to participants represents both an ethical and human rights concern [8]. The recent globalization of international clinical trials highlights relatively new questions as to whether conducting research in marginalized or oppressed populations can or should be acceptable.

The number and breadth of international and regional instruments displays the lack of clarity that exists within the biomedical fields of research. Declarations, by their very nature, are non-binding instruments that guide the conduct of research, but may hold mandatory rules within single institutions, not inter-state. Some have asserted that part of the problem is not that there is too little international standard setting but that there is too much of it [9]. We believe that issues arising in clinical trials are not limited to ethical concerns, but at times enter the world of international human rights law. We recognize the need for further discussion and the difficulties of conducting international research and the complexities of contemporary medical research in the developing world, particularly research amongst populations that are known to suffer systematic human rights violations- from here on called 'oppressed'. We recognize that in-light of existing cases of participation in rights and ethics violations, any new declarations or legal instruments must have the requisite teeth to bite when transnational companies and sovereign states engage in questionable foreign research with foreseeable negative consequences.

The development of new and innovative medicines is being hampered by the rising cost of clinical trials [1], with one estimate for the cost of bringing a drug to market as $2.6 billion, a 145% increase from 2003 [2]. Despite energy and resources devoted to study planning, protocol development, and physician reimbursement, many studies fail to recruit enough patients to be adequately powered, and a subset even fail to recruit *any* patients [3–5]. Even once recruited, patients may still choose to prematurely drop out of a trial, compromising the study's validity [6]. Tools and strategies that overcome challenges to recruitment and retention have the potential to reduce costs and so accelerate research, but this first requires a thorough understanding of the potential barriers. These include (1) organizational factors, (2) healthcare professional factors, and (3) patient factors [7, 8].

Many patients harbor misconceptions about trials; in a survey of nearly 6,000 patients, 37% thought their medical care would be better if they *did not* enroll in a trial, and 22% believed enrolling in a clinical trial would lead to them being "treated like a guinea pig" [9]. Such fears are not completely unfounded given that that participating in a trial is increasingly burdensome, with the median number of study procedures that patients must endure rising from 20 per protocol in 2000–2003 to 30 in 2008–2011 [10]. Listening effectively to patients at early stages may uncover patient-facing obstacles, facilitating effective planning and minimizing burden. Patient-centered approaches to study design and execution might even yield more successful studies [11] and methods to support higher levels of patient engagement have been successfully introduced by research groups such as the OMERACT group [12] and the I-SPY2 trial [13]. In both examples, patients helped resolve research challenges by (1) addressing undesirable aspects of trials, (2) surfacing new perspectives to researchers, (3) interacting directly with researchers, and (4) co-producing new resources that patients may find beneficial before, during and after the trials [14].

Such examples are few and far between, however, and the potential to prevent costly and avoidable protocol amendments [15] has stimulated interest to systematically involve patients in trial designs on a wider scale. However, deployment of patient-centered engagement models are challenging to implement and sustain over a period of time. Patient-powered research networks (PPRNs) might offer one useful model to streamline real-time patient input into clinical trial planning, having the advantage of inherent scalability, reaching patients

in their homes, and having lower barriers than traditional methods to ask multiple rounds of iterative questions [16].

MATERIALS AND METHODS

Study Population

Potential participant's information was collected from the clinical studies of children with Risk for Type 2 Diabetes . 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 May, 2018, and phone calls were made up until June 2018. 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).

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. 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 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. 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

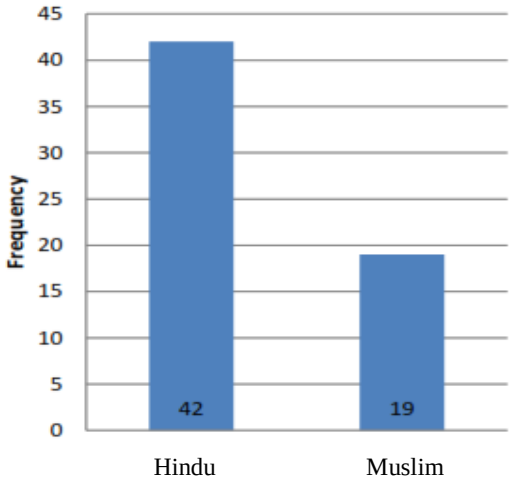
A Fischer's Exact Test was utilized to examine the association between study results (independent variable: normal/abnormal results) and willingness to participate in future studies (dependent variable: yes/no). Parents/legal guardian were asked to rank their willingness on a scale of 1-7, 1 being 'unlikely' 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.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 Hindu/Muslim and 42 (68.9%). 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's ethnicity



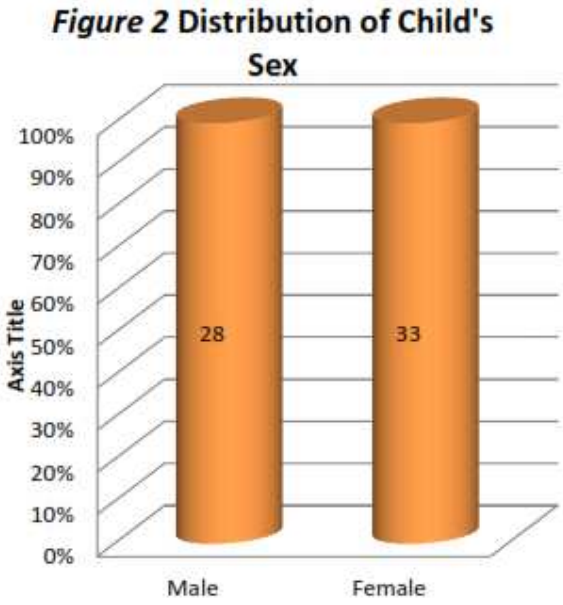
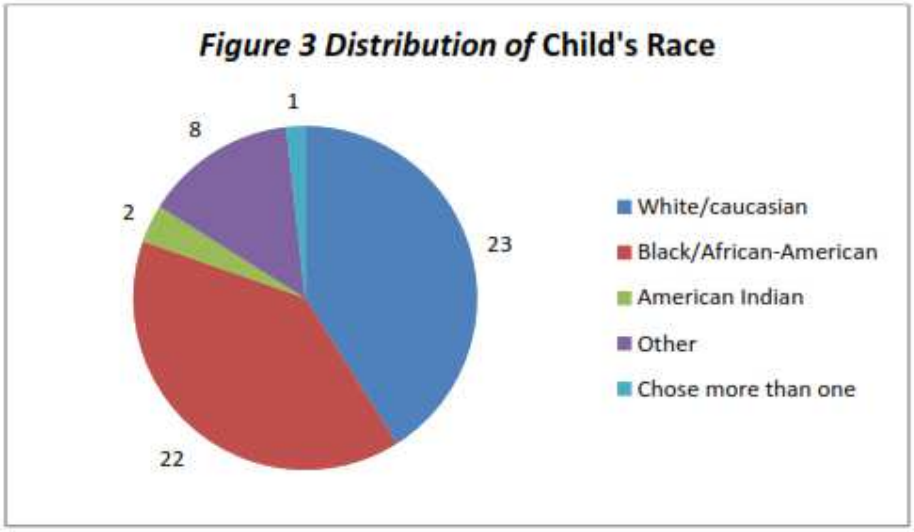


Figure 3 Distribution of Child's Race

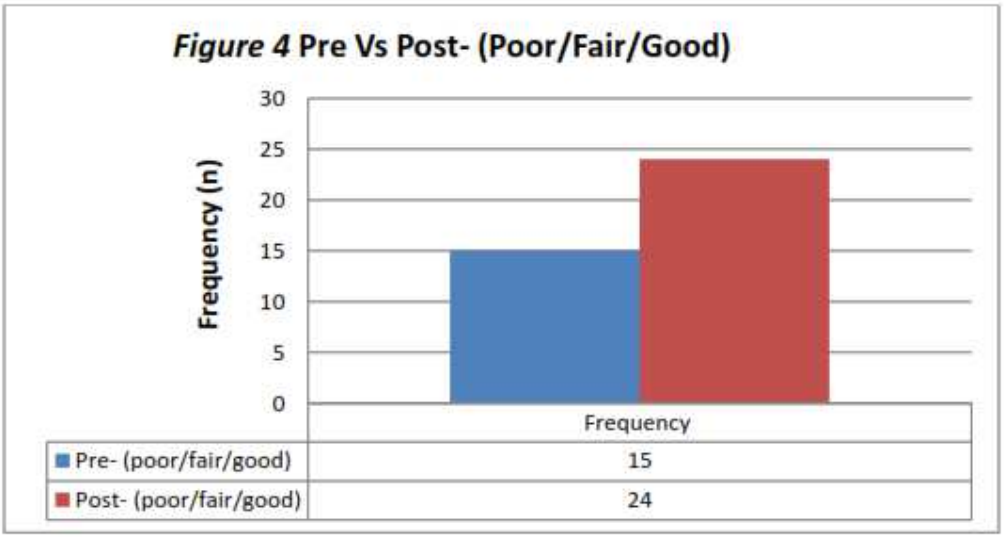


Specific Aim 1: To determine if study results were beneficial to the parents in recognizing their child's current health.

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 (Muslim or Hindu).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).

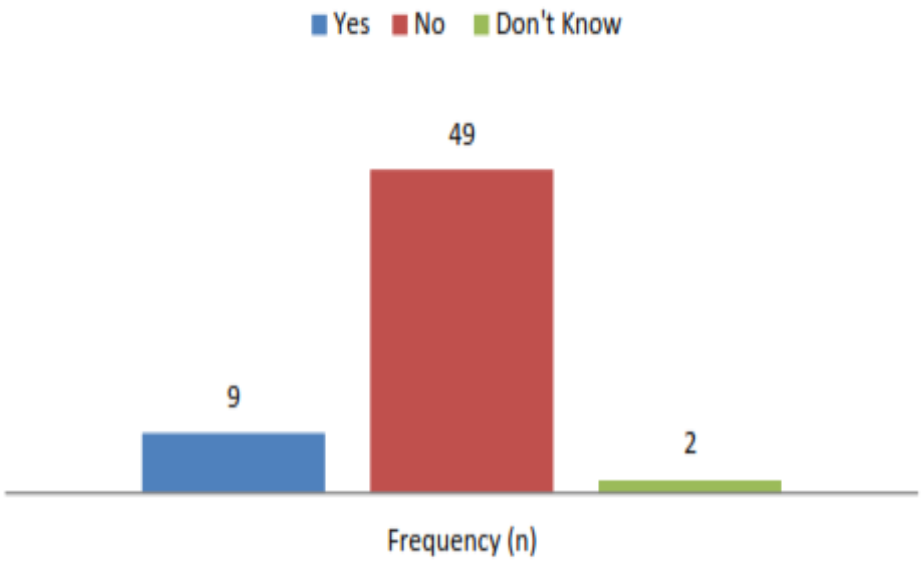
Table 7 Compared Child Visits for Normal and Abnormal Populations

	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.

Figure 6 Did study results influence the scheduling of doctor visits



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.

Figure 7 Did parents/legal guardians feel like the follow up results were helpful?

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. 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. There is little literature describing unexpected benefits, especially improved awareness of health or even lifestyle changes. 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).

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

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. An important opportunity exists for standardized practices and tools to ensure Children make well-informed decisions regarding their participation in clinical trials, using materials appropriate to their level of understanding. These tools would establish a baseline standard for the assent process and be made available to researchers, improving their ability to secure assent from young patients

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How to cite this article:
Ritu Jangra & Dr Pramod Singh Khatri. ***An Evaluation of Variations In Health Knowledge And Régimes After Participating In A Clinical Study.*** **Br J Bio Med Res , Vol.02, Issue 05, Pg.700-718, September - October 2018. ISSN:2456-9739 Cross Ref DOI : https://doi.org/10.24942/bjbmr.2018.337**

Source of Support: Nil **Conflict of Interest:** None declared.