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Research Article

An Evaluation of Aspects That Influence Patient Recruitment In Clinical Trials

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ABSTRACT

Our objective was to identify the key factors pertaining to patient participation in clinical trials, to better understand the identified low participation rate of patients in clinical study. This study investigated factors that influence Subject's decisions to participate in clinical trials and whether the impact of these factors differs from those of other medical specialties. Providing material in the patient's own language, explaining the study well, and elucidating how their participation might benefit others in the future may help to improve enrollment in clinical trials. Patients' motivations for trial participation included potential personal benefit and altruistic reasons. The majority of patients feel that participants should be informed of trial results and there is a group of patients who would like more detailed trial information.

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INTRODUCTION

Many studies have investigated the factors influencing patient participation in clinical trials from different areas of medicine. Some of them have attributed decisions regarding participation in clinical research to patients' gender, race, linguistic capabilities, and socioeconomic status. In addition to these personal characteristics, multiple extrinsic factors associated with the research process itself, the clinical staff with whom they interact, the quality of clinical care, and the communication from the research staff are known to play a role. Some of the reported motivating factors include how well the study was explained to them, a strong patient-physician relationship, the knowledge that their participation was going to benefit someone in the future, and compensation for participating. Other factors reported to function as barriers to participation include distrust in the doctors, risk of unknown side effects, and language differences.

The India spends 2 Million dollars annually on healthcare with as much as 15–20% being spent in acute care and emergency situations. Evidenced based medicine is dependent on information gained from well-run clinical trials to provide the answers needed to guide efficient and cost effective patient care. Clear evidence is lacking for many treatments, but research efforts are growing especially in emergency medicine. Projects and funding for research in this setting are not limited to the specialty of emergency medicine but often involving the collaboration of multiple specialties such as orthopedics, cardiology, pediatrics, and neurology both individually and as part of networks.

The first randomized controlled trial was published in October 1948.[1] Since then, both the design and analysis of clinical trials have become increasingly complex. Patient participation in clinical research is one of the main challenges faced by researchers today. The scale of the problem is not well documented, but one survey of recruitment that examined a cohort of 41 randomized controlled trials in the United States found that 34% of the trials recruited less than 75% of their planned sample.[2] The inability to recruit an adequate number of participants reduces the statistical power of the study and often leads to inconclusive results.[3-6]

A key yet understudied issue is the attitude of potential participants toward clinical research, particularly clinical trials. One systematic review identified the main barriers to participation in randomized controlled trials as (1) additional demands of a study, including procedures, appointments, travel problems, and cost; (2) preferences of patients regarding a particular treatment or no treatment; (3) worry caused by uncertainty of treatments or trials; and (4) concerns of patients about information and consent.[7] However, most of the articles that were reviewed pertained to hospital-based cancer research in the United States.

Two previous studies showed disparate results pertaining to patient attitudes toward participation in clinical trials. A study of outpatients in Denmark showed an overall positive attitude,[8] whereas a survey in Germany showed a low (25%) willingness to participate.[9]

Since the studies assessing barriers toward clinical trial enrolment have primarily focused on subspecialty patients,[7] the perspectives of the potential participants within the community remain largely unstudied. A better understanding of the perspectives of participants would likely increase the relevance of research and improve enrollment.[10-14]

Clinical trials are conducted across many countries and the success of a clinical trial will depend on many factors such as commitment of the sponsor, competency of the investigator, appropriate study design & statistical analysis, adequate resources and availability of trial subjects.

Recruitment of the subjects and retention of the enrolled subjects till completion of the trial will certainly decide the success of clinical trials. Low subject recruitment will prolong the trial duration and can have various negative implications[15-16]. The sponsor would find it difficult to meet timelines of regulatory submission and bear additional expenditure of prolonged trial. Inability to meet recruitment targets may cause premature closure of study sites and when it occurs at multiple sites, it may lead to termination of the trial. If enrollment of required number of subjects fails, it may affect the statistical power of the trial and validity of the data generated. Low subject recruitment will also affect the interest of the study team including the investigator, CRA, monitor and sponsor[17]. Therefore, poor subject recruitment is likely to impede successful evaluation of new drug interventions and adversely influence clinical trial programs.

Hypothesis

The Clinical Project was designed to test the following hypothesis: Are there certain modalities in a subject's life that has influenced them to participate in a clinical research study? The hypothesis was tested to determine the significance of each question in regards to its impact. The use of Chi Square will provide an accurate and efficient method of significance testing.

Specific Aims

The following specific aims were addressed in a subject survey to provide a conclusion on how to successfully recruit study subjects. More importantly, analyzing the data from respondents will allow the local research staff to implement strategies to prevent hindrances to the recruitment process.

Aim I: Identify the barriers to subject recruitment:
The aim focuses on evaluating any barriers that are preventing subjects from enrolling in a research study. In order to successfully enroll a subject into a research study, the barriers or rather failures have to be acknowledged and corrected.

Aim II: Identify the factors that impact a subject's consent to a clinical study:
Analyzing the factors with the most significant impact, the local research staff can be provided with insight on what methods work well for future subject recruitment. The factors with the greatest significance will be established as a continued standard of subject recruiting. This aim is in conjunction to Aim I.

Aim III: Analyzing the factors that establish relationships between the subject and site.
The role of the research staff is of crucial importance for the continuation of a research study. These staff members function as an extra safety net for a subject's health. Following enrollment, subjects will see the research staff annually and, in some cases, even as often as monthly. Questions regarding the efficacy of the site and site staff will be included in a survey in order to serve the needs of the research department at Medanta Hospital. Conclusions from those questions will be able to provide valuable insight on how current subjects feel about their time in the study. Subsequently these conclusions can also be utilized to prepare and accommodate future subjects.

DESIGN AND METHODOLOGY

To address the specific aims of the Clinical Project, a fifteen-question survey was developed. With the assistance of the site mentor, the survey was formulated to resemble certain aspects of a survey created by the Center for Information & Study on Clinical Research Participation (CISCRP) 8. The language of the survey was simplified to ensure that all subjects participating will easily understand the questions presented. In using a few of the top rated factors compiled by CISCRP, the survey utilized at Medanta Hospital distributed 13 of the 15 questions into

5 major domains:

a. Personal influence
    a. Questions 1, 2, and 3

b. Family influence
    a. Questions 4 and 5

c. Local Research Staff influence
    a. Questions 6, 7, 8, and 9

d. Financial influence
    a. Questions 10 and 11

e. Physician influence
    a. Questions 12 and 13

Illustration 4.2 provides a template of the questionnaire that subjects were responsible for completing. Question 14 was in place to measure subsequent attrition based on the subjects' responses. While the practicum steers away from the attrition argument, analyzing subject's likelihood of continued participation is a valued asset in the maintenance of patient satisfaction. The final question asks responders to recall on how they became involved in their research study.

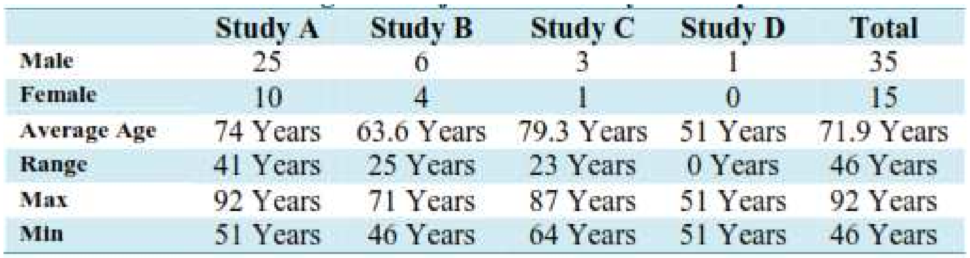
This question incorporates the idea of referral popularized by Clinical Trial Educators. Each question posed provided respondents with a possibility of five answer choices: strongly agree, agree, neutral, disagree, and strongly disagree. Following the data collection period, subject responses were then transcribed to a numerical value. Agree and strongly agree were to be deemed as "positive" responses eliciting a value of 4 and 5 respectively. Disagree and strongly disagree were designated as "negative" responses with a numerical value of 1 and 2. Neutral responses were treated as "no answer" and thus did not have an associative number transcribed to it. Before subjects were able to complete the survey, they were asked to read and sign an inform consent form (ICF) which detailed the study, the risks (or lack thereof) of the study, and the study's purpose. A series of previously approved ICF's were reviewed to provide a paradigm in which the survey study ICF was modeled after. Following their completion of the survey, subjects were given a copy of the ICF for their record. The ICF template approved by the IRB at Medanta Hospital can be seen from illustration 4.3. To maintain complete anonymity, the survey and ICF were kept separate from each other. While the survey was obtained through various methods, subjects were assured anonymity regardless of ascertainment method. Subjects who were available for in office follow-up visits were left in an examination room to fill out the survey.

After completion of the survey, the subject placed the survey into a lock-box as further verification of anonymity. Subjects who returned the survey via mail were able to do so with an unmarked envelope provided to them at the time their survey was sent. Although these subjects were also asked to return their ICF with the completed survey, the process of separating the ICF and placing the survey into a lock-box remained the same. The survey box and ICF envelope were kept separately and were not filed in any systematic order that would identify the ICF with its respective survey. The surveys were not viewed until closure of the study and the beginning of the data analysis process. The purpose of this anonymity was to encourage subjects to be honest in their responses without fear of how they would be perceived by the research staff.

Sample Demographic

In obtaining a normalized sample size, subjects were surveyed from four ongoing clinical trials at Medanta Hospital. The studies are designated by letters A-D to avoid any undue disclosure and identification of study protocol and materials. The subjects from Study A, C, and D have all had cardiac catheter procedures and stent placement. Study B subjects are currently enrolled in a cholesterol lowering medication study. There were 50 subjects from the four studies who were eligible to be surveyed. The eligible subjects were between the ages of 46 years and 92 years with an average age of 71.9 years. There were a total of 35 males and 15 females that were eligible for participation. Study A provided the majority of eligible subjects (70%). In contrast, Study D had only one subject eligible during the period of survey administration. Table 6.1 illustrates a complete distribution of subjects who were eligible to complete the survey. The distribution includes maximum/minimum age, male to female ratio, average age of eligible respondents.

Table 6.1: Eligible Subjects for Survey Participation



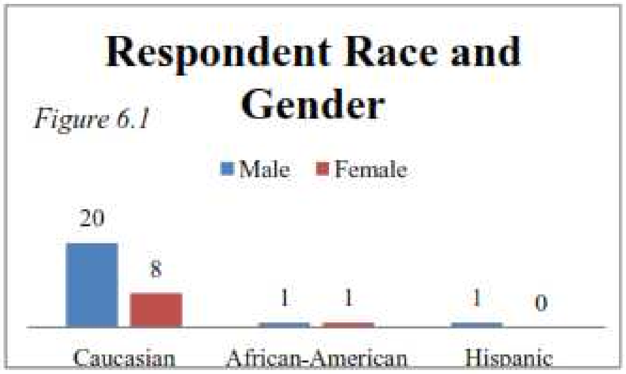
	Study A	Study B	Study C	Study D	Total
Male	25	6	3	1	35
Female	10	4	1	0	15
Average Age	74 Years	63.6 Years	79.3 Years	51 Years	71.9 Years
Range	41 Years	25 Years	23 Years	0 Years	46 Years
Max	92 Years	71 Years	87 Years	51 Years	92 Years
Min	51 Years	46 Years	64 Years	51 Years	46 Years

Additional inclusionary/exclusionary criteria were not included in the survey study. Subject participation hinged on three things: first the subjects must be enrolled in an open research trial at Medanta Hospital; second, the studies must be in the stages of enrollment or follow-ups; and lastly the subjects must complete an ICF before responding to the survey. Table 6.2 displays the distribution of 31 subjects who completed the survey. Average subject age from this distribution pool was 72.7 years with a majority of the respondents being male (71%).

Table 6.2: Subjects Who Completed the Survey

	Study A	Study B	Study C	Study D	Total
Male	14	5	2	1	22
Female	5	3	1	0	9
Average Age	75.9 Years	63.6 Years	84.3 Years	51 Years	72.7 Years
Range	30 Years	25 Years	4 Years	0 Years	46 Years
Max	92 Years	78 Years	87 Years	51 Years	92 Years
Min	62 Years	46 Years	83 Years	51 Years	46 Years

Subjects were included in the survey study regardless of race and gender. There were a total of 28 subjects that completed the survey. Figure 6.1 depicts a breakdown of the 31 respondents by race and gender.



The subjects were approached beginning of June, 2018, following Medanta Hospital's IRB approval of the survey study. The period of survey administration lasted until the July, 2018. Subjects who were contacted and have signed ICF's during this period were included in the final data analysis. The final sample size to analyze from was 31 subjects.

DATA ANALYSIS & RESULTS

Following IRB approval of the survey study, contact information and visit window dates were collected to prepare for data collection. Of the 50 eligible subjects, 36 received a survey either in office or by mail (72% of eligible). There were 3 subjects who declined to participate, all three with varying reasons. One subject felt that being a screen-failure would not have yielded appropriate data. Another subject felt the survey would be too time-consuming. The final subject to decline, did so due to a recent move out of state. One of the eligible subjects was in critical condition and was currently in a nursing care facility during the period of survey administration and contact was not made. Another subject passed away earlier in the year and thus contact was not made. Subjects were given a survey only after initial interest was expressed. Subjects who did not have a window visit date during the eligible administration period were contacted by phone. In total 26 subjects were contacted by phone, with nine unreturned messages despite multiple contact attempts. All of the subjects (15) who had in office follow-up visits completed a survey. As illustrated by table 4.1, the survey return rate across all four studies was quite outstanding.

Survey Distribution

Table 7.1	Study A	Study B	Study C	Study D	Total
Eligible Subjects	35	10	4	1	50
Surveys Administered	23	8	4	1	36
Surveys Returned	19	8	3	1	31
Unreturned Surveys	4	0	1	0	5
Declined	2	1	0	0	3
Unable to Reach	8	1	0	0	9
Critical Care/Decease	2	0	0	0	2

Study B and D had all of the administered surveys returned. The 100% return rate for Study B and D was perhaps a result of the small sample size (n= 11). Although Study C had a small enrollment number, a majority of the subjects (75%) returned the survey. Subjects in Study A (n=19) managed a high return rate (83%) despite the sheer number participants. The overall return rate amongst the four studies was slightly below (86%) the initial goal (90%). Subjects who refused to participate were contacted prior to administration of the survey therefore never received a survey. Every subject who was seen in office for a follow-up visit agreed and completed a survey. The three refusals were done via phone at time of initial subject contact.

The method of ascertainment was scrutinized to determine if a discrepancy existed. Subjects who completed the survey in office had similar responses to those who had the survey mailed to them. There were slight variations in the overall data between the two groups. Utilizing the associative number outlined in “Design & Methodology”, the distribution of subject survey who returned their surveys via mail had a mean score of 47.9 with a standard deviation of 9.5. The maximum score given to any subject in this subset was 62 and the minimum score given was 31. The 15 in-office respondents had a mean of 49.8 with a Score standard deviation of 7.5. The maximum score for these subjects was 64 and the minimum score was 36. The 31 subjects overall had a mean score (48.9) and standard deviation (8.5) that fell between the values of the separated groups.

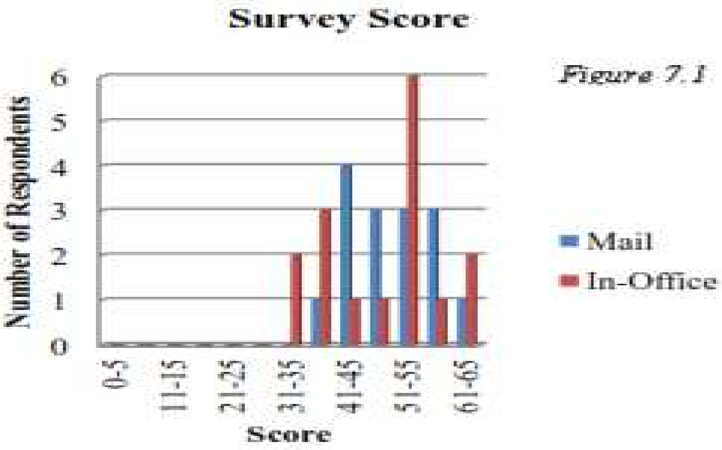


Figure 7.1

Personal Influence

Questions 1, 2, and 3 directed the subjects to respond to how they viewed their participation in a clinical research study. Responses indicated that a majority (74%) of the subjects joined a research study to get access to better medical care (Question 1). An overwhelming majority (87%) disagreed and even strongly disagreed with the idea that by participating in a study, they were gambling with their health (Question 3). Subjects responded rather positively to their role as a contributor to science (90%), with zero respondents in disagreement to this sentiment (Question 2). Neutrality was only present in a small minority (12%) of the overall responses for the three questions posed regarding the personal domain.

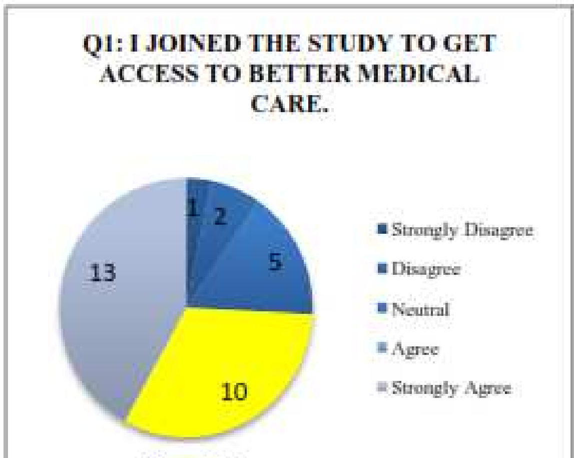


Figure 7.2

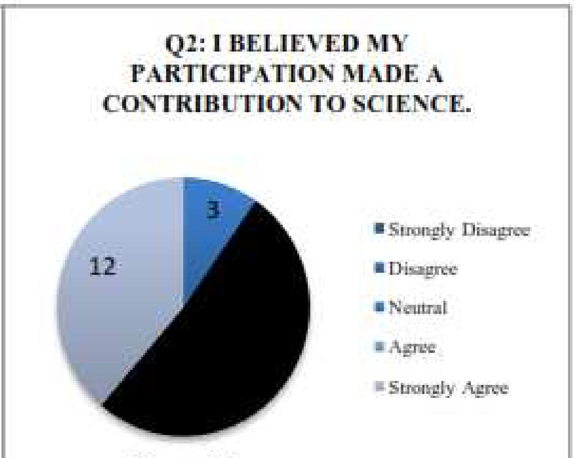


Figure 7.3

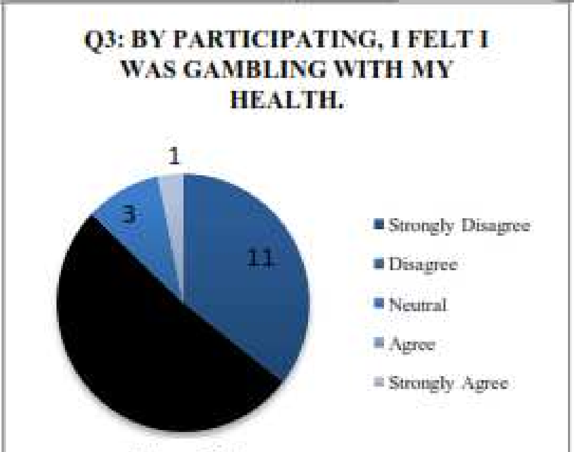


Figure 7.4

Family Influence

When asked about family influence and involvement respondents were seemingly ambivalent. Responses about how impactful family influence was in a subject's decision to join a research study were (19%). There were more patients (42%) who believed their family contributed to their decision compared those who did not believe (39%) that family influence was a factor (Question 4). Family involvement invoked a slightly more skewed distribution (Question 5). Respondents more frequently claimed (68%) that their family was office for follow-up visits as well as other medical appointments. Of the five domains into which the questions were designated, the family domain had the most "neutral" responses. Between the two questions that were posed to subjects, 16% of the responses did not have patients choosing agree or disagree. In comparing the family influence domain, responses distributed quite evenly among the 5 available response options. The highest majority for any given response between the two questions was only 42%, compared to a majority of 77% in questions regarding the research staff. While family members are not quite as influential in a subject's decision to participate in a research study, many of the subjects have been observed bringing a spouse or child during their office visit.

Figure 7.5

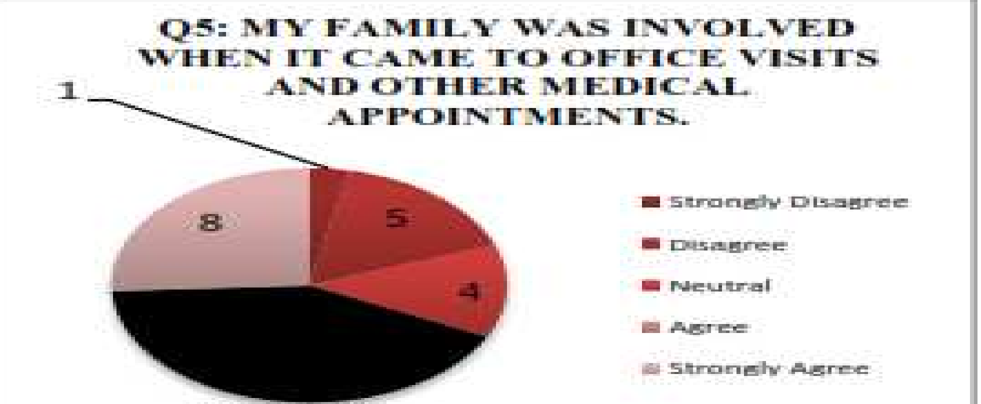


Figure 7.6

Local Research Staff Influence

Inquired about their experiences with the local research staff, respondents were overwhelmingly positive with almost all (98%) of the responders agreeing or strongly agreeing to statements. Of the four questions posed, only 3 of the responders provided a neutral answer. Those three neutral responses were in regards to the accessibility of the research office site (Question 8). Overall the responders did not feel negatively towards any of the 4 questions that were directed at them.

All of the respondents were in agreement that the research staff is knowledgeable about the studies (Question 8); more than half (52%) of the respondents strongly agreed to the statement and the remainder (48%) agreeing. A little less than three-quarters (74%) of respondents strongly felt that the research staff is friendly and inviting during follow-up visits in the office space. One of the duties of a research coordinator consists of calling and sending out reminder letters to a subject when their follow-up visit window is near. Subjects are mailed a letter one week before their target window date to remind them of their follow-up visit. Once the subject calls to coordinate a date and time when they are able to follow-up, it is up to the coordinator to ensure these subjects are reminded by phone one day before their visit date. All of the responders (100%) were in agreement that the reminder calls and letters they receive from the research staff is greatly appreciated. More than half (65%) of the subjects strongly agreed when asked about their appreciation of reminders and the remaining 35% simply agreed. Compared to the other four domains, questions about research staff were the only ones to elicit all positive responses.

None of the responders strongly disagreed or even disagreed with statements about the research staff. Each of the three respondents who selected neutral when asked about site accessibility associated their response with an explanation. All three believed that their lack of transportation to the research site for follow-up visits contributed to their neutrality on the matter. Although the attitude was generally positive regarding the research site, a little less than half (45%) of the respondents felt strongly about site access. Unlike other domains, two of the four questions pertained more to subject satisfaction. Question 8 and question 9 were in place to gauge the subject's subsequent contentment after successful recruitment and enrollment in their clinical trial. The responses from this domain have tremendous implications for the research staff. The number one goal for a research site is to enroll as many subjects as possible for a particular study. In keeping subjects satisfied, the line of communication stays open and a level of trust can be established to encourage continued participation. Since the staff becomes the primary safeguard for a subject's overall health during their time in the study, any acknowledged faults can be amended and any praises can be utilized in interactions with future research subjects.

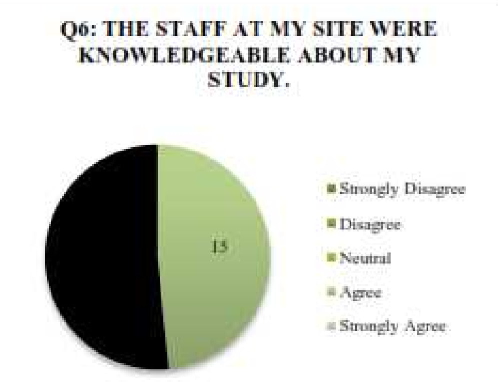


Figure 7.7

Figure 7.8

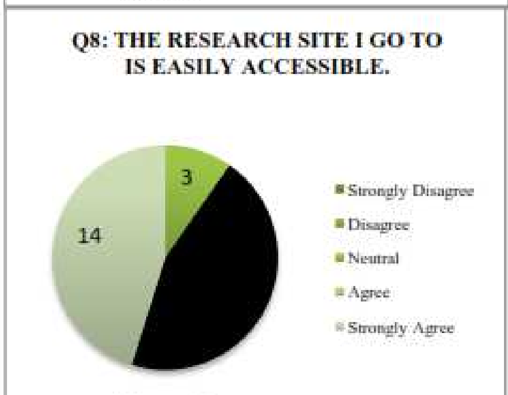


Figure 7.9

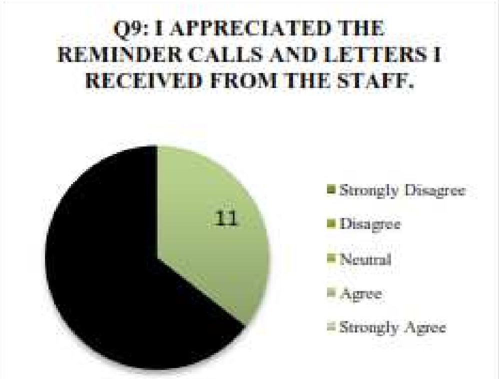


Figure 7.10

Financial Influence

Contrary to the positive responses regarding the research staff, questions targeted at financial incentives were met rather negatively. A majority of the respondents (71%) disagreed that their participation in a research study were motivated by free medication and treatment (Question 10). Even more subjects (81%) disagreed with the idea that monetary compensation contributed to Between the four different studies in which data was collected from, only one study (Study B) offered subjects compensation for their time and travel expenses. Study B also provided subjects with vouchers to cover the expenses of the medication associated with their study. Although Study A, C, and D lack monetary incentives, subjects had the cost of their device excluded from the final bill. Subjects in those three studies also had less frequent office visits than those who are participating in Study B. Following hospital discharge, subjects in Study A, C, and D are only required to follow-up annually in office. Any other visits are done via phone. For Study B, subjects are required to attend office follow-ups monthly for the first 6 visits. Following this period, subjects are then limited to bi-monthly visits, then ultimately subjects will only be required to follow-up annually.

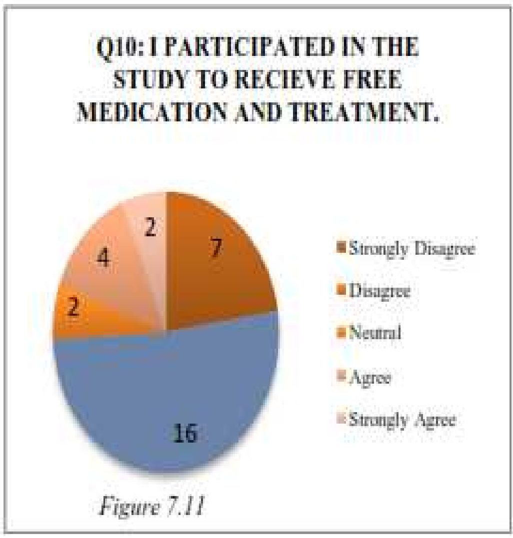


Figure 7.11

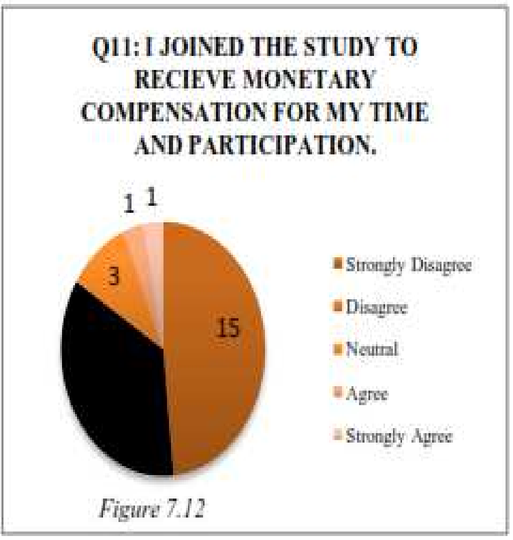


Figure 7.12

Physician Influence

Prior to participating in a clinical research study, subjects have previously built a rapport and relationship with Medanta Hospital credentialed cardiologists. One of the leading factors that prevent subject enrollment in clinical studies is the distrust of physicians and the research community. In evaluating how subjects feel about their physicians, it becomes of great relevance in preventing laymen distrust of medical personnel. It seems that while distrust remains a major hindrance, the Medanta Hospital research staff and team of physicians have successfully combated this. All 31 respondents indicated that they heard about their respective research study from either a physician or by a research coordinator. Questions regarding a subject's network of physicians elicited overall positive responses, similar to that of the local research staff. According to the 31 subjects, almost all of them (97%) believed that by participating in the research study, they have access to the best physicians. The statement did not elicit any negative responses from responders and only one subject felt neutral about the matter. It should be noted that while the subject felt neutral about the superiority of his/her cardiologist, the subject did not feel the research study was a health gamble. A majority of responders (74%) felt their primary care physicians supported their decision to participate in a research study. One subject disagreed with the sentiment while the remaining subjects (23%) provided a neutral response.

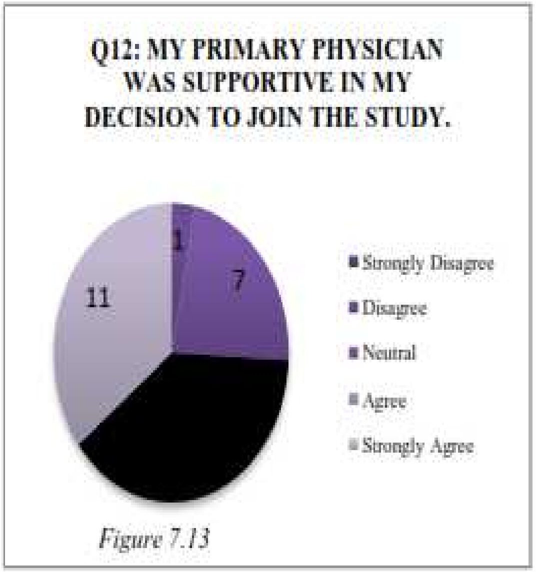


Figure 7.13

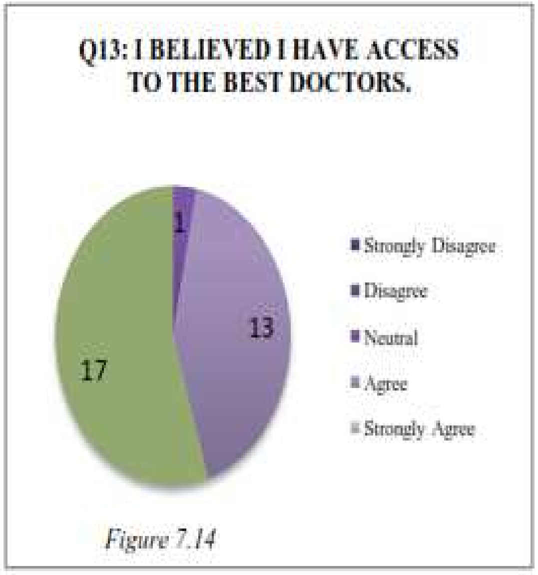


Figure 7.14

Continued Participation

The final aspect of the subject survey also yielded strongly positive responses. With yet another overwhelming majority (90%), respondents indicated they were likely to continue their participation in their respective research study. Although a small minority (7%) responded negatively to the inquiry, the two responses was merely an "unlikely" to continue participation.

None of the subjects felt strongly negative about the question. More than 60% of the positive responders indicated a very strongly likelihood of continued participation. The results from the question yielded a distribution similar to that of statements regarding the local research staff. While the ultimate goal of any research study is to retain 100% of their subjects, the respondents who did not respond positively to the question provided an explanation. The subject who remained neutral indicated that transportation could prevent future follow-up visits. The two subjects who responded negatively to the question implicated their advancing age as the issue in preventing continued participation. The subjects felt that the inconvenience of travel associated with physical immobility warranted discontinuation of their participation. Despite the subjects' knowledge regarding the anonymity of the survey, their unsolicited explanation is a great asset to be utilized for future research subjects. A few subjects who managed to respond positively to the question stipulated that their continued participation was dependent on if they survived the next year. While it is difficult to ascertain the level seriousness these subjects' displayed, their advanced age and innumerable health conditions make the statement a serious cause for concern.

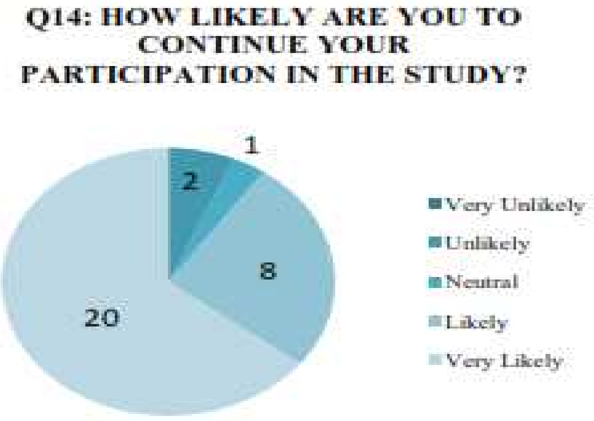


Figure 7.15

The relatively small p-value indicates that more subjects than expected responded positively to the sentiment. This implies that the accessibility to better medical care is significantly influences in a subject's decision to join a research study. According to table 7.3 the idea that a contribution to science was being made has strong impact on a subject's decision to join a research study. The frequency distribution and very small p- value illustrates extreme statistical significance.

Similar to the previous question, Question #3 yielded similar significance. The distribution leaned more negatively than expected. While the subjects did not believe that they experienced a health gamble, the small p-value indicates that the sentiment has an impactful influence on participating in a clinical trial of the 14 questions subjected to chi-square testing, Question #4 yielded the only "not statistically significant". For the most part the distribution frequency yielded similar values to what is expected. There is not enough evidence to suggest that family influence as having any sway on a subject's decision making process.

Q1: I joined the study to get access to better medical care.

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	13	41.94	13	41.94
Agree	10	32.26	23	74.20
Neutral	5	16.13	28	90.33
Disagree	2	6.45	30	96.78
Strongly Disagree	1	3.23	31	100.01

Table 7.2

Chi Square	17.226
DF	4
Pr> ChiSq	0.0017

While Question #5 was statistically significant, the strength of significance was not as strong. The rather small p-value implies that unlike family influence, family involvement had a significant influence on a subject's decision to participate in a clinical research study. Staff knowledge of the subject's research study was extremely significant.

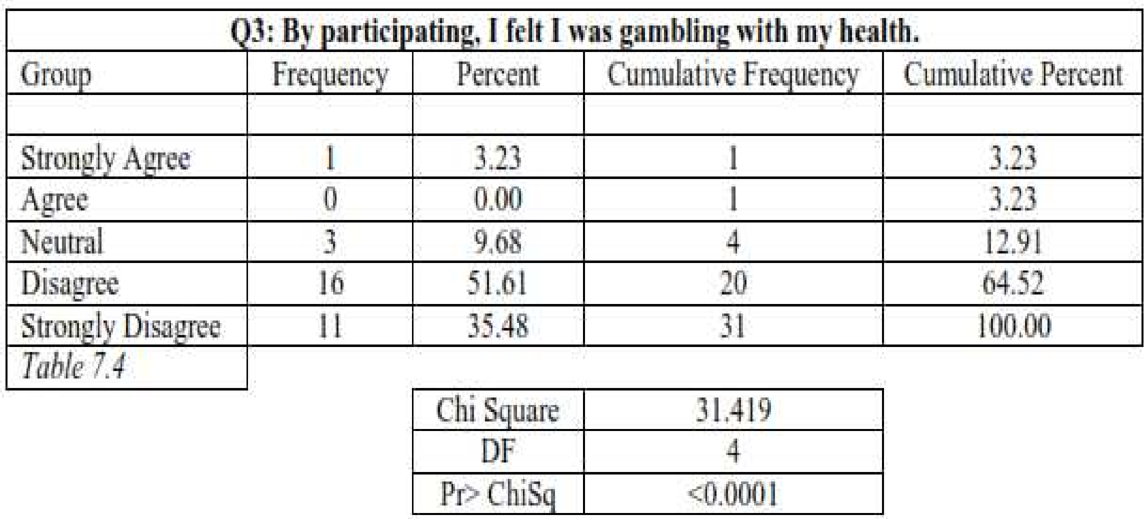
Q2: I believed my participation made a contribution to science.

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	12	38.71	12	38.71
Agree	16	51.61	28	90.32
Neutral	3	9.68	31	100.00
Disagree	0	0.00	31	100.00
Strongly Disagree	0	0.00	31	100.00

Table 7.3

Chi Square	34.968
DF	4
Pr> ChiSq	<0.0001

The positive responses and very small p-value indicates staff knowledge is quite influential in a subject's decision to participate in a clinical research trial. With the largest Chi-Square values and an extremely small p-value, the staff's positive attitude has significant implications in a subject's decision. The p-value is also indicative that the distribution was dramatically more positive than expected. Site accessibility plays a pivotal role in a subject's decision. This is most evident by the small p-value indicating extreme statistical significance. It should also be noted that subjects who provide explanations with their responses mention transportation and accessibility rather vehemently as a hindrance to their participation in a clinical trial. Similar to Question #7, the large Chi-Square value and extremely small p-value indicates an extreme level of statistical significance. The staff's reminder calls and letters are of great influence in a subject's continued participation.

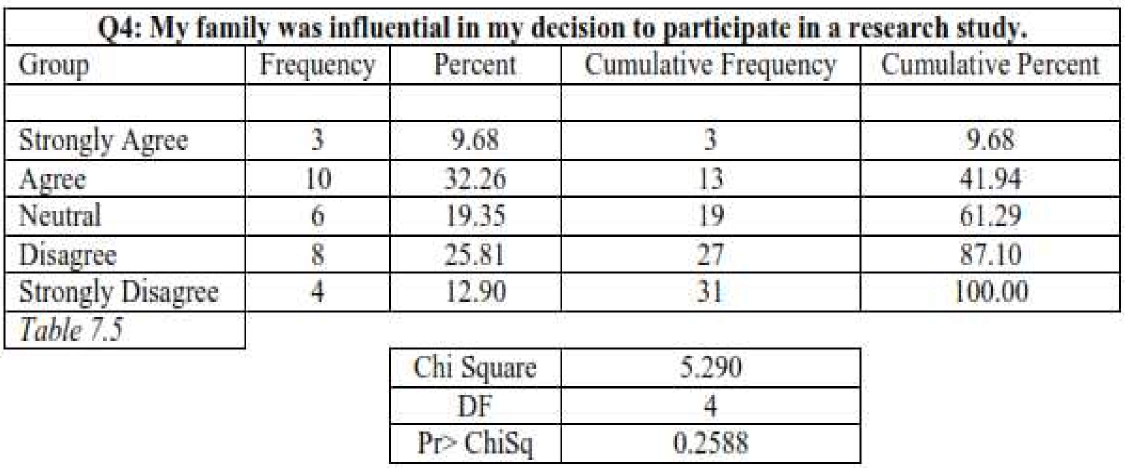


Q3: By participating, I felt I was gambling with my health.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	1	3.23	1	3.23
Agree	0	0.00	1	3.23
Neutral	3	9.68	4	12.91
Disagree	16	51.61	20	64.52
Strongly Disagree	11	35.48	31	100.00

Table 7.4

Chi Square	31.419
DF	4
Pr> ChiSq	<0.0001

With one of the higher p-values, Question #10 still possesses an extreme statistical significance. The unexpected distribution heavily favors negative responses. This data favors the majority of the subjects and suggests that free medication and treatment are reasons for participation.Much like Question #10, the level of statistical significance indicates that subjects viewed monetary compensation rather negatively. It is with great certainty that the data suggests that monetary compensation is not influential in a subject's clinical trial participation.The small p-value indicates that a subject's primary care physician's support was statistically significant enough to influence their decision.



Q4: My family was influential in my decision to participate in a research study.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	3	9.68	3	9.68
Agree	10	32.26	13	41.94
Neutral	6	19.35	19	61.29
Disagree	8	25.81	27	87.10
Strongly Disagree	4	12.90	31	100.00

Table 7.5

Chi Square	5.290
DF	4
Pr> ChiSq	0.2588

With overwhelmingly positive responses, subjects felt that they had access to the best doctors. The very small p-value indicates that the data is statistically significant enough to attribute as an influence in the subject decision making process. The results from Question 14 were of extreme statistical significance. The data implies that a subject's decision to continue participation was made retroactively when they agreed to enroll in a research study.

Q5: My family was involved when it came to office visits and other medical appointments.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	8	25.81	8	25.81
Agree	13	41.94	21	67.75
Neutral	4	12.90	25	80.65
Disagree	5	16.13	30	96.78
Strongly Disagree	1	3.23	31	100.00
Table 7.6				

Chi Square	13.355
DF	4
Pr> ChiSq	0.0097

Q6: The staff at my site was knowledgeable about my study.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	16	51.61	16	51.61
Agree	15	48.39	31	100.00
Neutral	0	0.00	0	100.00
Disagree	0	0.00	0	100.00
Strongly Disagree	0	0.00	0	100.00
Table 7.7				

Chi Square	46.581
DF	4
Pr> ChiSq	<0.0001

Q7: The staff at my site was friendly during my visits.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	24	77.42	24	77.42
Agree	7	22.58	31	100.00
Neutral	0	0.00	0	100.00
Disagree	0	0.00	0	100.00
Strongly Disagree	0	0.00	0	100.00
Table 7.8				

Chi Square	69.806
DF	4
Pr> ChiSq	<0.0001

Q8: The research site I go to is easily accessible.

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	14	45.16	14	45.16
Agree	14	45.16	28	90.32
Neutral	3	9.68	31	100.00
Disagree	0	0.00	0	100.00
Strongly Disagree	0	0.00	0	100.00

Table 7.9

Chi Square	33.677
DF	4
Pr> ChiSq	<0.0001

Q9: I appreciated the reminder calls and letters I received from the staff.

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	20	64.52	20	64.52
Agree	11	35.48	31	100.00
Neutral	0	0.00	0	100.00
Disagree	0	0.00	0	100.00
Strongly Disagree	0	0.00	0	100.00

Table 7.10

Chi Square	53.032
DF	4
Pr> ChiSq	<0.0001

Q10: I participated in the study to receive free medication and treatment.

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	2	6.45	2	6.45
Agree	4	12.90	6	19.35
Neutral	2	6.45	8	25.80
Disagree	16	51.61	24	77.41
Strongly Disagree	7	22.58	31	99.99

Table 7.11

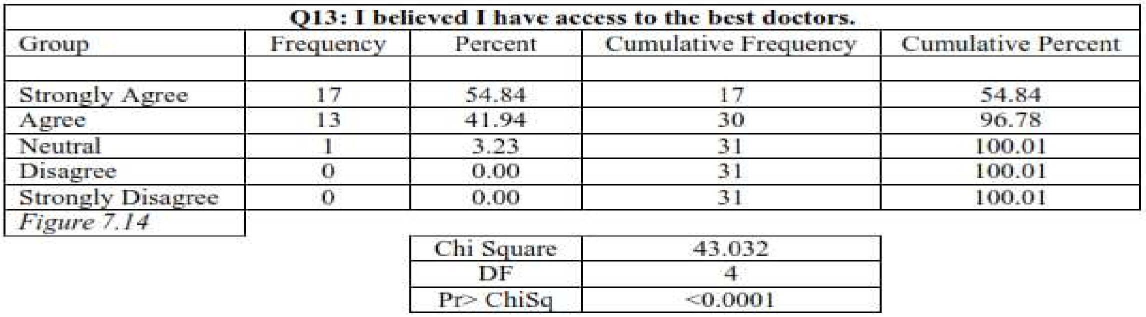
Chi Square	22.065
DF	4
Pr> ChiSq	0.0002

Q12: My primary physician was supportive of my decision to join the study.

Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	11	35.48	11	35.48
Agree	12	38.71	23	74.19
Neutral	7	22.58	30	96.77
Disagree	1	3.23	31	100.00
Strongly Disagree	0	0.00	31	100.00

Table 7.13

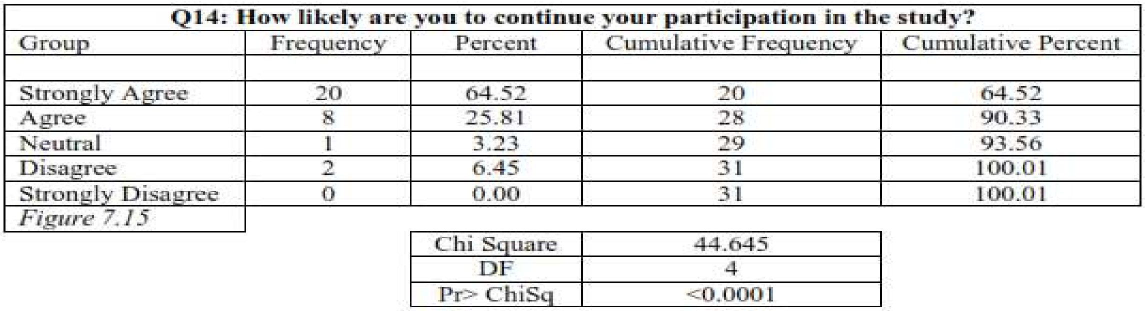
Chi Square	19.806
DF	4
Pr> ChiSq	0.0005



Q13: I believed I have access to the best doctors.				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	17	54.84	17	54.84
Agree	13	41.94	30	96.78
Neutral	1	3.23	31	100.01
Disagree	0	0.00	31	100.01
Strongly Disagree	0	0.00	31	100.01

Figure 7.14

Chi Square	43.032
DF	4
Pr> ChiSq	<0.0001



Q14: How likely are you to continue your participation in the study?				
Group	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Strongly Agree	20	64.52	20	64.52
Agree	8	25.81	28	90.33
Neutral	1	3.23	29	93.56
Disagree	2	6.45	31	100.01
Strongly Disagree	0	0.00	31	100.01

Figure 7.15

Chi Square	44.645
DF	4
Pr> ChiSq	<0.0001

Tables 7.2-7.15 provide a frequency distribution of the responses with respect to each individual statement/question posed. The tables utilized the Chi-square method for testing the appropriate influence of each statement. With the exception of Question # 4, all of the results were found to be either very statistically significant or extremely statistically significant. In stratifying the questions by their respective domain, an overall Chi-Square test was performed. The data yielded Chi-Square values of 11.355 (Personal Influence), 14.129 (Family Influence), 186.242 (Research Staff influence), 40.581 (Financial Influence), and 56.871(Physician Influence). The values were tested under the following parameters: $\alpha=0.05$ with four degrees of freedom.

LIMITATIONS OF THE STUDY

Limitation Due to Time

Due to the short length of the internship, time was a major hindrance to the data collection process. There was only three months available to administer the survey to study subjects. Some of the subjects had to be contacted via phone multiple times before a survey was returned. There were a total of 15 eligible subjects that did not have surveys administered to them. With more time, more contact attempts could be made. While there were a few refusals, all of the subjects who appeared in the office for their follow-up visit completed the survey.

Limitation Due to Methodology

Subjects who were contacted via phone to participate in the study were mailed a survey and ICF to complete. After two weeks, the subjects received a follow-up phone call, many of these subjects indicated that they did not receive a survey or had misplaced their previous one. Two subjects returned surveys but did not include their ICF. Subsequent contact to obtain the ICF's were unsuccessful and their surveys to had to be disposed.

Limitation Due to Sample Demographic

Eligible subjects' advanced age made contact quite difficult. There were a total of eight unreturned messages; all eight messages were left with the subjects' family member. Following the initial contact, contact was unsuccessful in subsequent attempts. During an attempt to contact one subject, a family member informed the study coordinator that the subject had passed away months ago. Another subject was being cared for at critical care facility and unable to participate.

Limitation Due to Design

While the Medanta Hospital research department has seven ongoing studies, only four were considered open studies. To allow for a standardize sample, surveys were only made available to those who currently in an open study. This meant the study must either be enrolling or in the follow-up phases of the clinical trial process.

DISCUSSION & CONCLUSION

The Chi-Square values lead to a rejection of the null hypothesis (There is no association between factors and their influence on clinical trial participation). Data collected during the project indicates that there are indeed influences that impact a subject's decision to participate in a research study. While the strength of these influences cannot be statistically determined, the subjects' agreement and disagreement can provide some conclusions. The modalities that seem to have the most impact seem to be that of the local research staff. This seems rather counterintuitive; however, because the research staff has had contact with a subject prior to the ICF process, it would seem to make complete sense. Prior to signing the ICF and agreeing to participate in the study, subjects are given a complete and in-depth breakdown of the study. The research staff is also made available to answer any questions or concerns. This process seems to be of great influence, given that every respondent answered positively to the question regarding the staff's knowledge of their research study. This can lead to the formation of a trusting relationship that eases the subjects into making that decision to participate. On the contrary, influences of a family member was not at all significant in the decision-making process. However, when associated with the presence of a family member during office visits and other medical appointments, the data revealed statistical significance.

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