



Knowledge And Perception About Clinical Research in Indian Population

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(Received: 02 August 2023)

Revised: 14 September

Accepted: 07 October)

KEYWORDS

Clinical Trial,
Clinical Research,
Knowledge,
Perception

ABSTRACT:

Clinical trials play a vital role in the ongoing expansion of medical knowledge and healthcare. The way the public perceives and understands clinical research can influence regulatory policies, direct research priorities, and contribute to the overall development of the sector. Barriers to participation in clinical trials, such as distrust, insufficient awareness, and misconceptions about clinical research, have been recognized as significant challenges. The objective of current study is "To assess the clinical Research Knowledge & Perception among participants." 158 participants scored in between 0 to 15 point out of 32 points questions which shows that they had no prior knowledge or poor knowledge on clinical trials and 13 participants had scored between 16 to 29 points which shows that they had average knowledge on clinical trial and only 5 participants had scored between 30 to 32 points which shows that they had excellent knowledge on clinical trial. The results conclude that majority of participants had no knowledge and had negative thinking about the clinical trial in the questionnaire. This study concludes that there is need of clinical trials awareness program to improve the knowledge of public. However, our findings show that public awareness initiatives are necessary to encourage participation in clinical trials.

INTRODUCTION

Clinical trials serve the crucial purpose of evaluating novel approaches for cancer treatment, exploring preventive measures, and assessing new diagnostic or screening methods. These trials play a pivotal role in advancing medical knowledge and improving healthcare outcomes. Moreover, they generate substantial economic benefits by fostering job creation within the healthcare, pharmaceutical, and research sectors, thereby contributing to enhanced profits for the involved companies and national institutions.¹

The potential of autonomous, native medical research and the development of innovative therapies are not just appealing but also essential for burgeoning economies like

India, which is on track to become the world's most populous nation and a prominent global economy by the mid-21st century. Public consciousness, perceptions, and resulting attitudes regarding clinical research can influence regulatory frameworks, direct research focal points, and influence the sector's expansion. Skepticism, insufficient awareness, and misunderstandings related to clinical research are recognized as principal obstacles hindering participation in clinical trials.²⁻⁵

Despite the crucial role played by the media in disseminating information about unethical practices, persistent inaccuracies and unfavorable portrayals of clinical research continue to prevail.^{6,7} Such media representations have the potential to create an 'exploitative' perception of research sponsors,



fostering distrust, diminished support, and opposition to clinical research. Several instances highlight this issue. For instance, Medindia.com, self-described as 'Asia's premier health portal,' contains an article stating, 'Due to intensive and strict Animal guidelines using animals in India too has become a very problem, so the drug companies have shifted their trials to humans rather to animals.' Following the unfortunate deaths of four teenage girls participating in the Human Papilloma Virus (HPV) vaccine trial, a formal investigation revealed unrelated causes, yet the media continues to accuse the Indian government of subjecting the public to testing dangerous vaccines, labeling them as 'guinea pigs.'⁸⁻¹⁰ Public opinion polls reported that 39% believed pharmaceutical companies failed to serve consumers (higher than 19% in 1997), without mentioning that 60% thought pharmaceutical companies did a good job serving consumers (higher than 44% in 2004).^{3, 10-12}

OBJECTIVES

To assess the clinical Research Knowledge and Perception among participants.

MATERIALS AND METHODS

Inclusion & Exclusion Criteria:

The inclusion criteria are mentioned a) Participants above 18+, b) Both the gender c) Participants from the various hospitals from Chhattisgarh, D) Willing to participate on proper process (ICF). Exclusion criteria a) Relatives of Clinical Trial Participants, B) Health care providers from the hospitals.

SURVEY INSTRUMENTS

A validated Questionnaire was used in this study and the evaluation of participants' perceptions of clinical research involved the administration of a questionnaire comprising 32 questions. The questionnaires were meticulously designed to explore perceptions across five distinct categories. These categories aimed to gauge the perceptions regarding the value that research brings, perception regarding Motivation of participation in research, perception regarding compliance on research, perception regarding trust of research entities and perception regarding myths of research entities.

ETHICAL APPROVAL

This study was passed from Sanjeevani Cancer Hospital Institutional Ethical Committee and recruitment was started after approval.

RESULTS:

DEMOGRAPHIC DISTRIBUTION

The study has conducted on 176 participants, the data analysis indicated that 53.4% (94 participants) of the participants well in urban areas, while the majority, accounting for 46.6% (82 participants), hail from rural areas (Table1, Fig.1). The finding from the survey reveals a notable imbalance in gender representation, with a higher percentage of male participants 62.5% (110 individuals), while 37.5% (66 individuals) were female (Table1, Fig.2). The employment part shows that 77.3% (136 individuals), were in the workforce. Conversely, 7.9% (14 individuals) were without employment, and 14.7% (26 individuals) belonged to diverse categories such as housewives and retirees (Table1, Fig.3). Educational attainment indicated that 15.3% (27 participants) had completed less than a high school education, 27.3% (48 participants) had finished high school, and a substantial majority, comprising 57.4% (101 participants), had pursued college or advanced studies (Table1, Fig.4).

Age wise distribution shows that it has diverse age range, including participants from 18 years old and those over 65. The breakdown of respondents is as follows: 78.4% (138 participants) fall within the 19-40 age range, 21.0% (37 participants) are between 41 and 65 years old, and 0.56% (1 participant) is 65 years old or above (Table1, Fig.5). The mean age of the participants is 32.14 ± 11.66 (mean \pm SD). An analysis of their monthly income distribution reveals that 25.5% (45 participants) reported having no income, and 0.56% (1 participant) reported income within the range of up to Rs 5000. Additionally, 31.2% (55 participants) fell into the income bracket of Rs 5001-15000, 29.5% (52 participants) reported incomes in the range of Rs 15,001-25,000, 9.9% (16 participants) in the range of Rs 25,001-35,000, 3.4% (6 participants) in the range of Rs 35,001-45,000, and 0.56% (1 participant) reported an income of Rs 45,000 (Table1, Fig.6). The average income of the participants is 18934 ± 8880 (mean \pm SD).



Table-1 Demographic Distribution

CRITERIA	
Age Group	
18-40	137
41-65	37
Above 65	2
Gender	
Male	105
Female	71
Education Level	
Less than high school	48
High School	39
College or More	89
Employment	
Employed	118
Unemployed	23
Others	35
Monthly Income	
No income	84
<5000	0
5,001-15,000	48
15,001-25,000	30
25,001-35,000	6
35,001-45,000	7
Above 45,000	1
Area	
Urban	56
Rural	120

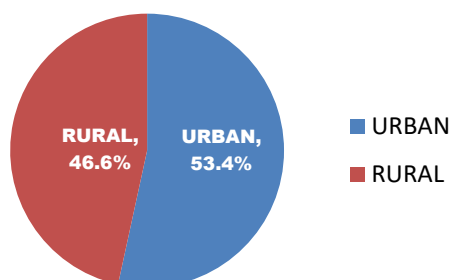
**AREA**

Fig.1 Area wise distribution

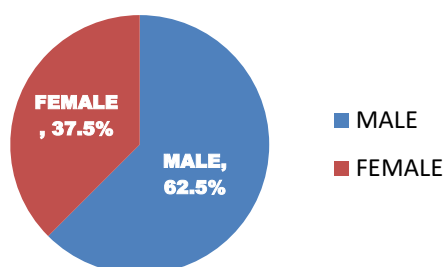
GENDER

Fig.2 Gender wise distribution

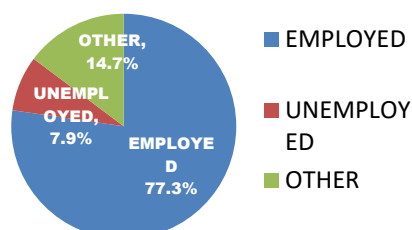
EMPLOYMENT

Fig.3 Employment wise distribution

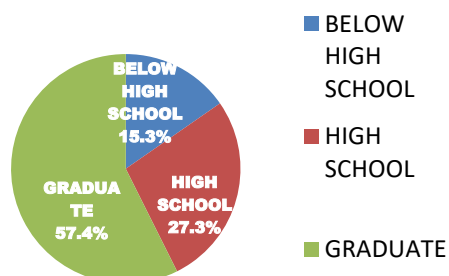
EDUCATION

Fig.4 Education wise distribution

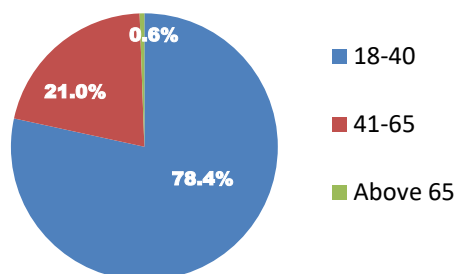
AGE

Fig.5 Age wise distribution

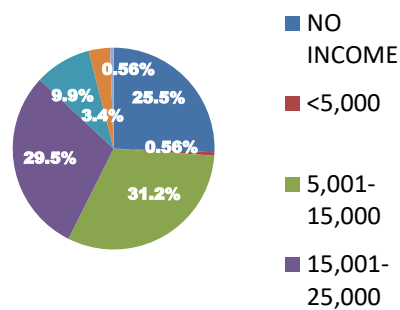
MONTHLY INCOME

Fig.6 Monthly Income wise distribution



CLINICAL RESEARCH KNOWLEDGE AND PERCEPTION

Table-2 Perceptions regarding the value

	QUESTIONS	TRUE	FALSE	NOT AWARE
Q1	Clinical research benefits society.	26	101	49
Q2	Clinical research harms society.	97	37	42
Q3	Clinical research is an essential step in developing new treatments.	29	98	49
Q4	Hospitals that participate in clinical research provide better healthcare	30	96	50
Q5	Experiments on humans are essential to developing new treatments	33	96	47

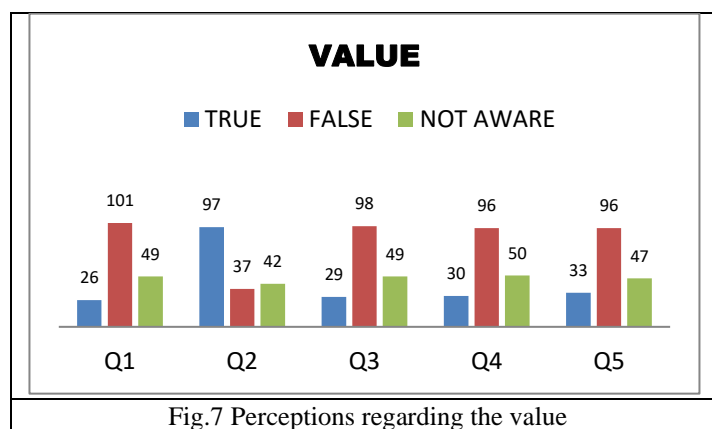


Fig.7 Perceptions regarding the value

The questionnaire data for the study participants regarding perceptions of the value responses shows that Q1, 26 participants responded true, 101 responded false and 49 participants responded as not aware. In Q2, 97 participants responded true, 37 responded false and 42 participants responded not aware. In Q3, 29 participants responded true, 98 responded false and 49 participants responded not aware. In Q4, 30 participants responded true, 96 responded false and 50 participants responded not aware and In Q5, 33

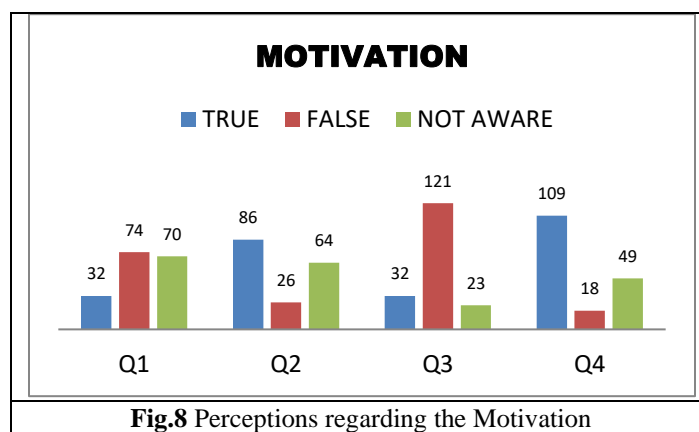
participants responded true, 96 responded false and 47 participants responded not aware (Table 2, Fig. 07). Overall 142 participants scored in between 0 to 1 point out of 5 points questions which shows that they had no prior knowledge or poor knowledge on clinical trials and 21 participants had scored between 2 to 3 points which shows that they had average knowledge on clinical trial and 13 participants had scored between 4 to 5 points which shows that they had excellent knowledge on clinical trial (Fig. 12).

Table-3 Perceptions regarding the Motivation

	QUESTIONS	TRUE	FALSE	NOT AWARE
Q1	The most important reason for developing new treatments is the advancement of science.	32	74	70
Q2	The most important reason for developing	86	26	64



	new treatments is financial gain.			
Q3	Participation in research is entirely voluntary.	32	121	23
Q4	Altruism is the only valid reason for participation in research	109	18	49



Response on Perceptions regarding the motivation reflects that Q1, 32 participants responded true, 74 responded false and 70 participants responded not aware. In Q2, 86 participants responded true, 26 responded false and 24 participants responded not aware. In Q3, 32 participants responded true, 121 responded false and 23 participants responded not aware and in Q4, 109 participants responded true, 18 responded false and 49 participants responded not

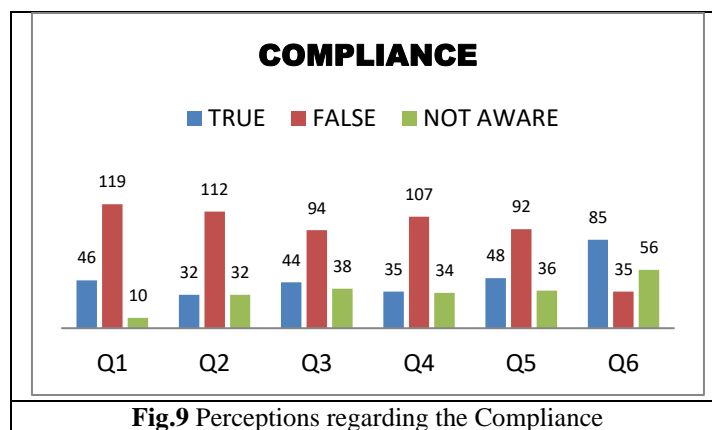
aware (Table3, Fig.08). Overall 150 participants scored in between 0 to 1 point out of 5 points questions which shows that they had no prior knowledge or poor knowledge on clinical trials and 24 participants had scored between 2 to 3 points out of 5 points questions which shows that they had average knowledge on clinical trial and 2 participants had scored between 4 points which shows that they had excellent knowledge on clinical trial (Fig.12).

Table-4 Perceptions regarding the Compliance

	QUESTIONS	TRUE	FALSE	NOT AWARE
Q1	Volunteers in clinical research get adequate compensation for their participation.	46	119	10
Q2	Participants in clinical research get adequate compensation for any adverse outcomes	32	112	32
Q3	Confidentiality of research participants is adequately protected.	44	94	38
Q4	Volunteers in clinical research get adequate information about the research they participate in	35	107	34
Q5	Researchers make sure the maximum safety of research participants	48	92	36



Q6	Harmful events occurring during a clinical trial must be due to experimental treatment.	85	35	56
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The responses on perceptions of the conduct of research shows Q1, 46 participants provided True, while 119 participants provided False, and 10 participants were not aware. In Q2, 32 participants responded True, 112 responded False, and 32 were not aware. Q3 showed that 44 participants responded True, 94 were False, and 38 were not aware. In Q4, 35 participants provided true, 107 were False, and 34 were not aware. Similarly, for Q5, 48 participants had responded true, 92 were False and 36 were not aware. Lastly,

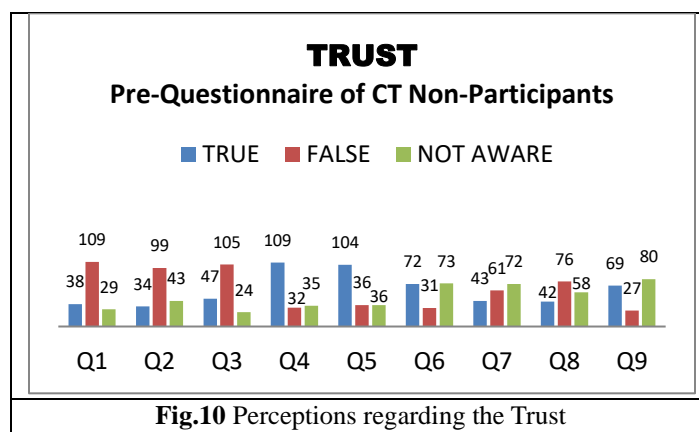
in Q6, 85 responded True, 35 responded False, and 56 were not aware (Table4, Fig.09). Overall 121 participants scored in between 0 to 1 point out of 6 points questions which shows that they had no prior knowledge or poor knowledge on clinical trials and 42 participants had scored between 2 to 4 points which shows that they had average knowledge on clinical trial and 13 participants had scored between 5 to 6 points which shows that they had excellent knowledge on clinical trial (Fig.12).

Table-5 Perceptions regarding the Trust

	QUESTIONS	TRUE	FALSE	NOT AWARE
Q1	The government always adequately protects the public against unethical clinical research.	38	109	29
Q2	Clinical research information provided by pharmaceutical companies can be trusted	34	99	43
Q3	Clinical research information provided by academic institutions can be trusted.	47	105	24
Q4	If you decide not to participate in research your doctor will not give you good care.	109	32	35
Q5	Doctors force their patients to participate in research.	104	36	36
Q6	Human participants in clinical research are treated like experimental animals ('human	72	31	73



	Guinea Pigs').			
Q7	Confidentiality is a matter of importance to research participants.	43	61	72
Q8	All the results of clinical research are made available to the public.	42	76	58
Q9	The media accurately describes clinical research.	69	27	80



In the assessment of study participantson trust in research, a set of nine questions was administered through a questionnaire to 176 participants revealed diverse responses across the questions. In Q1, 38 participants provided true, while 109 responded false and 29 were unaware. In Q2, 34 participants answered true, 99 answered false, and 43 were not aware. Q3 showed that 47 participants answered true, while 105 answered false, and 24 were not aware. In Q4, 109 participants responded true, 32 participants responded false, and 35 were unaware. In Q5, 104 participants responded true, 36 participants responded false, and 36 were unaware. In Q6, 72 participants responded true, 31 participants responded false, and 73 were unaware. In Q7,

43 participants responded true, 61 participants responded false, and 72 were unaware. In Q8, 42 participants responded true, 76 participants responded false, and 58 were unaware and in Q9 69 participants responded true, 27 participants responded false, and 80 were unaware (Table5, Fig.10). Overall 100 participants scored in between 0 to 1 point out of 9 points questions which shows that they had no prior knowledge or poor knowledge on clinical trials and 68 participants had scored between 2 to 7 points which shows that they had average knowledge on clinical trial and 8 participants had scored between 8 to 9 points which shows that they had excellent knowledge on clinical trial (Fig.12).

Table-6 Perceptions regarding the Myth

	QUESTIONS	TRUE	FALSE	NOT AWARE
Q1	Clinical Trial Volunteers are Guinea Pig.	138	32	6
Q2	Once you decide to participate in a clinical trial you will not able to change your mind.	80	35	61



Q3	Being in clinical research is expensive and is not covered by insurance.	109	32	35
Q4	If someone who is trying to participate in a clinical trial and the research team told him that he is not eligible to be in the trial. It Seems unfair.	43	28	105
Q5	Clinical trials are always dangerous.	35	24	117
Q6	To participate in a clinical trial a person needs to live near the trial site	108	23	45
Q7	Only the people who are terminally ill can participate in Clinical trials.	21	28	127
Q8	Clinical trials are the last resort for cures.	13	38	125

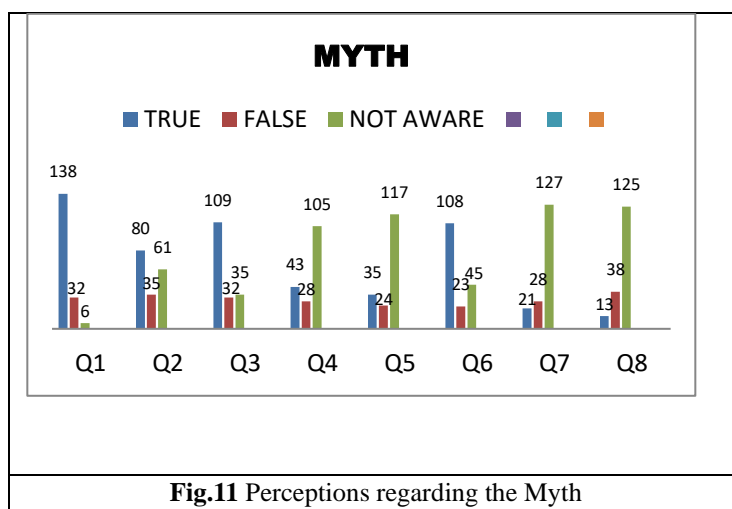


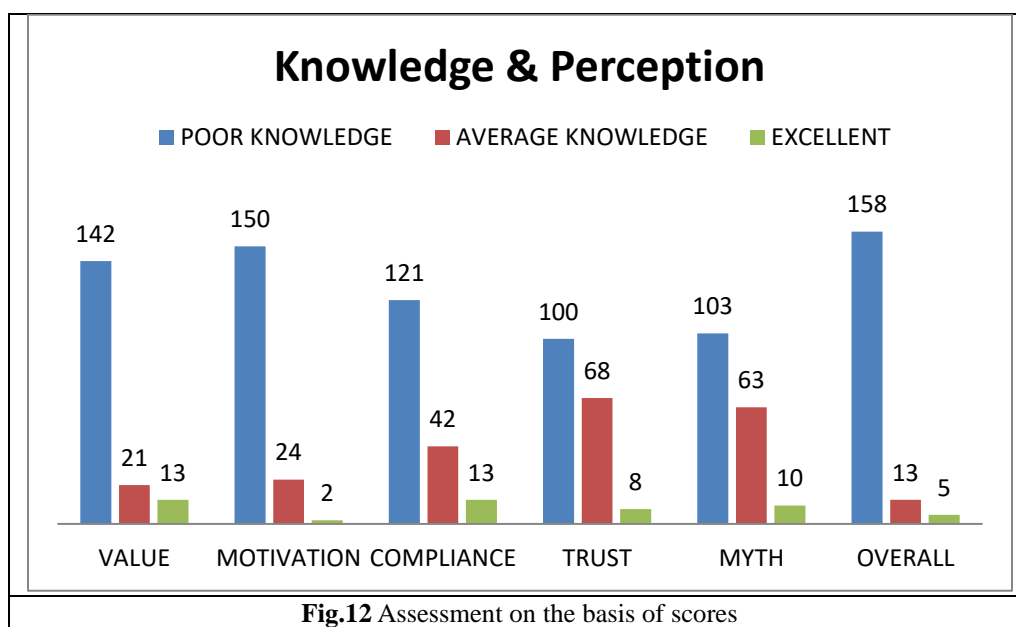
Fig.11 Perceptions regarding the Myth

Upon analyzing the questionnaire data on perceptions regarding myths associated with research entities, distinctive patterns emerged across multiple questions. In Q1 revealed that 138 participants provided true, while 32 responded false and 6 were unaware. In Q2, 80 participants answered true, 35 answered false, and 61 were not aware. Q3 showed that 109 participants answered true, while 32 answered false, and 35 were not aware. In Q4, 43 participants responded true, 28 participants responded false, and 105 were unaware. In Q5, 35 participants responded true, 24 participants responded false, and 117 were unaware. In Q6, 108 participants responded true, 23 participants responded false, and 45 were

unaware. In Q7, 21 participants responded true, 28 participants responded false, and 127 were unaware. In Q8, 13 participants responded true, 38 participants responded false, and 125 were unaware (Table 6, Fig. 11). Overall 103 participants scored in between 0 to 1 point out of 8 points which shows that they had no prior knowledge or poor knowledge on clinical trials and 63 participants had scored between 2 to 6 points which shows that they had average knowledge on clinical trial and 10 participants had scored between 7 to 8 points which shows that they had excellent knowledge on clinical trial (Fig. 12).

**Table-7** Assessment on the basis of scores

	POOR KNOWLEDGE	AVERAGE KNOWLEDGE	EXCELLENT
VALUE	142	21	13
MOTIVATION	150	24	2
COMPLIANCE	121	42	13
TRUST	100	68	8
MYTH	103	63	10
OVERALL	158	13	5



The assessment on the basis of scores on five ways of perceptions Value, Motivation, Compliance, Trust And Myth shows that, 158 participants scored in between 0 to 15 point out of 32 points questions which shows that they had no prior knowledge or poor knowledge on clinical trials and 13 participants had scored between 16 to 29 points which shows that they had average knowledge on clinical trial and only 5 participants had scored between 30 to 32 points which shows that they had excellent knowledge on clinical trial (Table7, Fig.12). The result shows that, the majority of participants had no knowledge and had negative thinking about the clinical trial in the questionnaire.

DISCUSSION

Our result engaged a total of 176 participants, who had no prior exposure to clinical trials. Age wise distribution shows that it has diverse age range, including participants under 18 years old and those over 65. The breakdown of respondents is as follows: 78.4% (138 participants) fall within the 18-40 age range, 21.0% (37 participants) are between 41 and 65 years old, and 0.56% (1 participant) is 65 years old or above. The finding from the survey reveals a notable imbalance in gender representation, with a higher percentage of male participants 62.5% (110 individuals), while 37.5% (66 individuals) were female.



According to a similar study done by Wei Du et al, 196 (55% white vs. 45% African American (AA)) suitable patients were included in the analysis out of 218 participants enrolled. The intervention arm had a little increase in therapeutic clinical trial enrolment, but it was not statistically significant. In addition, there was no discernible improvement in patients' views towards clinical trials at the posttest. However, after controlling for stage, AA women had a reduced enrolment.¹³ According to a similar study done by Oriana Awwad et al, approximately 20.5% of respondents have previously participated in a CT. Approximately 68.3% and 50.1% of respondents had good understanding and a favourable attitude towards CTs, respectively. Good knowledge was associated with male gender, higher education and healthy condition; while older age was associated with a poor knowledge. Positive attitudes were predicted by female gender, higher, and past engagement. Knowledge and attitude were shown to have a very slight positive connection. In terms of attitudes, the majority of respondents (85.3%) believe that CTs are done ethically in Jordan; yet, only 52.9% are comfortable participating. Knowledge and perception had a moderately favorable connection (Spearman's $r = 0.275$, $p = 0.001$). Participating in a CT has a major impact on knowledge, attitudes, and perceptions.¹⁴

Our study has conducted on the perspectives of 176 participant individuals. The evaluation of participant's perceptions of clinical research involved the administration of a questionnaire, comprising 32 questions. Questionnaire for participants analyzing aggregated data and assessing their knowledge and perceptions regarding the Value, Motivation, Compliance, Trust And Myth,¹⁵ 158 participants scored in between 0 to 15 point out of 32 points which shows that they had no prior knowledge or poor knowledge on clinical trials and 13 participants had scored between 16 to 29 points out of 32 points which shows that they had average knowledge on clinical trial and 5 non-participants had scored between 30 to 32 points out of 32 points which shows that they had excellent knowledge on clinical trial. So that our result shows that the majority of Clinical trial non-participants had no knowledge on clinical trial and by providing proper awareness program we can familiarize them with the clinical trial.

A similar study performed by Ravindra. B. Ghooi et al, A total of 5000 questionnaires were collected from the public population in Jordan, revealing that 43.4% (2171/5000) demonstrated knowledge on the subject. The public's understanding was found to be correlated with factors such as female gender (OR = 1.493, 95% CI = 1.280-1.741, $p < 0.001$), possession of a bachelor's degree (OR = 1.853, 95% CI = 1.592-2.157, $p < 0.001$), having children (OR = 1.433, 95% CI = 1.162-1.768, $p = 0.001$), and having first-degree relatives with co-morbid conditions (OR = 1.669, 95% CI = 1.431-1.946, $p < 0.001$). Despite the Jordanian public displaying commendable genetic awareness, they expressed reservations about the integration of genetics in clinical practice. Notably, all positive public views and the majority of concerns were significantly associated with genetic knowledge ($p < 0.001$).¹⁵ A similar study was conducted by the Yun Jung Choi A study was conducted to assess the knowledge and perceptions of clinical research among the general public in Korea. A total of 400 Seoul residents without prior experience in clinical trial participation were chosen as a representative sample of the population in Seoul, considering age and gender. To mitigate selection bias, every fifth passerby was approached for an interview, and if in a cluster, the person on the far right side was selected. Written instructions were incorporated into the questionnaire to ensure consistent survey application. Following a pilot test involving 40 subjects, the survey was conducted face-to-face in December 2014. To examine how perception influences behavior, perception scores were compared between those willing to participate and those unwilling. A significantly higher percentage of respondents claimed awareness of clinical research and knowing someone who participated, both $p < 0.001$, in comparison to India. However, the willingness to participate was notably lower at 39.3%, a statistically significant difference from India's 58.9% ($p < 0.001$). The primary motivating factor for participation was treatment benefits, followed by financial gain. Safety concerns emerged as the primary reason for refusal, followed by fear and lack of trust. Public awareness and educational programs addressing these negative perceptions and knowledge gaps are crucial for fostering increased public engagement in clinical research.¹⁰



Another study conducted by Jennifer Cunningham-Erves et al, The paired-sample t-test revealed significant increases in unadjusted mean scores for knowledge ($p < .001$), trust in medical researchers ($p < .001$), and willingness to participate in clinical trials ($p = .003$) after town halls in the overall sample. After adjusting for gender and education, all three outcomes remained statistically significant for the entire sample (knowledge: $p < .001$; trust in medical researchers: $p < .001$; willingness: $p < .001$) and for African Americans (knowledge: $p < .001$; trust in medical researchers: $p = .007$; willingness: $p = .005$). However, for Latinos, the significance in willingness to join was no longer observed (knowledge: $p < .001$; trust in medical researchers: $p = .034$, willingness: $p = .084$). In a similar study conducted by Sang Hui Chu et al., the perception of clinical trials (CTs) was assessed using a scale ranging from 0 (strongly disagree) to 10 (strongly agree). Respondents demonstrated a clear understanding of the necessity of CTs ($M = 7.27$, $SD = 2.15$), harbored moderately favorable views towards CTs ($M = 5.32$, $SD = 2.31$), and perceived these CTs as relatively safe ($M = 4.71$, $SD = 1.90$). Twenty-five percent of participants expressed their willingness to take part in a CT in the future. Factors such as the perceived eventual advantages of CTs, awareness, positive sentiments, safety, and the perceived need emerged as significant predictors of the desire to engage in CTs.¹⁷

CONCLUSION

This study concludes that common people should be given proper awareness about the clinical research and raising awareness about clinical research is crucial. It helps people understand the importance of participating in trials, advancing medical knowledge, and ultimately improving healthcare outcomes. However, our findings show that public awareness initiatives are necessary to encourage participation in clinical trials.

ACKNOWLEDGMENT

The authors would like to thank the Sanjeevani Cancer Hospital Institutional Ethical Committee for providing the approval to conduct the study.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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