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JCHR (2023) 13(6), 2688-2705 | ISSN:2251-6727



A study on the impact of awareness program on knowledge and perception about clinical research in Indian population

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(Received: 02 September 2023 Revised: 14 October Accepted: 07 November)

KEYWORDS

Clinical Trial, Clinical Research, Knowledge, Perception

ABSTRACT:

India has become a significant hub for clinical research (CR) in the past decade, marked by a series of regulatory modifications aimed at promoting CR growth and safeguarding patient rights. Insufficient awareness of clinical trials has been recognized as a hindrance to participating in such trials, a challenge that may be particularly pertinent in minority populations that are frequently underrepresented. The absence of trial awareness stands out among various barriers to clinical trial participation. The primary objective of the study is to assess the impact of awareness program on clinical Research Knowledge and Perception of participants. 176 Participants above 18+ of both the genders were included in the study. Result shows in Post questionnaire, 2 participants scored in between 0 to 15 point, 140 participants had scored between 16 to 29 points and 34 participants had scored between 30 to 32 points. The result concludes that, the majority of participants improved their clinical research knowledge after awareness session.

INTRODUCTION

India has become a significant hub for clinical research (CR) in the past decade, marked by a series of regulatory modifications aimed at promoting CR growth and safeguarding patient rights. Recent changes in the country encompass mandatory registration of ethics committees, delineation of conditions necessary for conducting clinical trials, and establishment of guidelines for determining compensation in cases of trial-related injuries. Lexamining the prevailing attitudes and understanding of clinical research (CR) within the general population is imperative for the development of more effective awareness initiatives.

Clinical trials (CTs) are widely acknowledged as the premier research methodology for systematically assessing the efficacy of healthcare interventions.⁴

Exploring the public's understanding and attitudes regarding participation in clinical trials (CTs), as well as identifying the factors that shape these perspectives, is pivotal for the successful implementation of clinical studies. ⁵⁻⁶ Global initiatives have been ongoing for an extended period to assess the public perception of clinical trials and the factors impacting participation. Within the Australian context, a qualitative study involving interviews with breast cancer patients revealed a limited understanding of the significance

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JCHR (2023) 13(6), 2688-2705 | ISSN:2251-6727



and procedural aspects of clinical trials.⁷ Within the Japanese context, the level of trust in physicians emerged as a significant factor influencing participation, with a noteworthy impact. Moreover, there was a negative perception towards the concepts of placebo, randomization, and double-blind trials.⁸⁻⁹

In an ideal scenario, clinical trials should be linked with altruistic motives and a foundation of trust. Society anticipates individuals to engage in clinical trials driven by altruism, while expecting other stakeholders involved in the clinical trial process to be sufficiently trustworthy. This trust is essential to ensure that participating individuals are treated with dignity, their well-being and rights are upheld, and their safety is adequately protected. The evolution of Good Clinical Practice norms contributes to these objectives, with various countries, including India, issuing guidelines for clinical trial professionals. 10-11

Insufficient awareness of clinical trials has been recognized as a hindrance to participating in such trials, a challenge that may be particularly pertinent in minority populations that are frequently underrepresented. The absence of trial awareness stands out among various barriers to clinical trial participation. ¹²⁻¹³ In this study we tried to assess and improve the knowledge and conduct awareness about clinical trials in Indian population.

OBJECTIVES

To assess the impact of awareness program on clinical Research Knowledge and Perception of 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. The participants assessed by the abovementioned questionnaire as pre questionnaire and post questionnaire on an interval of Awareness session.

ETHICAL APPROVAL

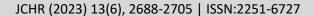
This study was passed from Sanjeevani Cancer Hospital Institutional Ethical Committee and recruitment was started after approval.

RESULTS:

DEMOGRAPHIC DISTRIBUTION

The study has conducted on 176 participants, the data analysis indicated that higher percentage of male participants 62.5% (110 individuals), while 37.5% (66 individuals) were female 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. 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. The mean age of the participants is 32.14±11.66 (mean+-SD). An analysis of their monthly income distribution reveals that 25.5% (45 participants) reported having no income. The average income of the participants is 18934±8880 (mean+-SD).

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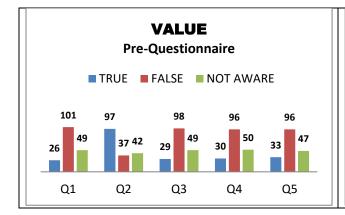


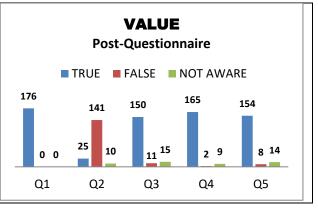


Clinical Research knowledge and perception assessment pre and post awareness session

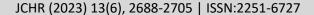
Table-1 Perceptions regarding the value assessment pre and post awareness session

| | | | Pre-A | wareness | | Post-Awareness | | | |
|----|---|----|-------|--------------|-------|----------------|-------|--------------|-------|
| | QUESTIONS | | FALSE | NOT AWARE | SCORE | TRUE | FALSE | NOT AWARE | SCORE |
| Q1 | Clinical research benefits society. | 26 | 101 | 49 | 26 | 176 | 0 | 0 | 176 |
| Q2 | Clinical research harms society. | 97 | 37 | 42 | 37 | 25 | 141 | 10 | 141 |
| Q3 | Clinical research is an essential step in developing new treatments. | 29 | 98 | 49 | 29 | 150 | 11 | 15 | 150 |
| Q4 | Hospitals that participate in clinical research provide better healthcare | 30 | 96 | 50 | 30 | 165 | 2 | 9 | 165 |
| Q5 | Experiments on humans are essential to developing new treatments | 33 | 96 | 47 | 33 | 154 | 8 | 14 | 154 |





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| Fig.1 Perceptions regarding the value in pre- | Fig.2 Perceptions regarding the value in post- |
|---|--|
| questionnaire | questionnaire |

Table-2 Comparison of perceptions regarding the Value between pre and post awareness session

| Column A | Pre questionnaire |
|-------------------------------------|--------------------|
| vs. | vs. |
| Column B | Post questionnaire |
| Paired t test | |
| P value | < 0.0001 |
| P value summary | **** |
| Significantly different (P < 0.05)? | Yes |
| One- or two-tailed P value? | One-tailed |
| t, df | t=16.36, df=4 |

The pre-questionnaire data for perceptions of the value of research shows Q1, 26 participants responded true, 101 responded false and 49 participants responded 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 1, Fig.1). After providing awareness session to all the 176 participants, there was a notable shift in the responses found in post questionnaire. In response to Q1, all participants choose True. In Q2, 25 participants responded true, 141 responded false and 10 participants responded not aware. In Q3, 150 participants responded true, 11 responded false and 15 participants responded not aware. In Q4, 165 participants responded true, 2 responded false and 9 participants responded not aware. And In Q5, 154 participants responded true, 8 responded false and 14 participants responded not aware. (Table 1, Fig.2)

The Pre questionnaire date reveals, 142 participants scored between 0 and 1 out of 5 points, which shows that they had no prior knowledge or poor knowledge on clinical trials and 21 participants had scored between 2 and 3 points, indicating that they had average knowledge on clinical trial and 13 participants had scored between 4 and 5 points, which shows that only 13 participants had excellent knowledge of clinical trials. Post Questionnaire data shows, 3 participants scored between 0 and 1 points, 14 participants had scored 2 to 3 points and 159 participants had scored 4 to 5 points out of 5 points which shows that majority of participants improved their clinical research knowledge after awareness session. The individual questions Score in pre-questionnaire shows for Q1, Q2, Q3, Q4 and Q5 as 26, 37, 29, 30 and 33 respectively from 176. This reveals that very few participants have the knowledge about clinical research. In the post-questionnaire the findings are 176, 141, 150, 165 and 154 respectively and it reflects that there is significant improvement on the knowledge and perception regarding clinical research. The same can be seen on Table-2 which is proving with the P Value < 0.0001.

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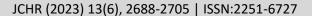




Table-3 Perceptions regarding the Motivation assessment pre and post awareness session

| | | | Pre-Qu | estionnaire | | Post-Questionnaire | | | |
|----|--|-----|--------|--------------|-------|--------------------|-------|--------------|-------|
| | QUESTIONS | | FALSE | NOT AWARE | SCORE | TRUE | FALSE | NOT AWARE | SCORE |
| Q1 | The most important reason for developing new treatments is the advancement of science. | 32 | 74 | 70 | 32 | 167 | 1 | 8 | 167 |
| Q2 | The most important reason for developing new treatments is financial gain. | 86 | 26 | 64 | 26 | 55 | 103 | 18 | 103 |
| Q3 | Participation in research is entirely voluntary. | 32 | 121 | 23 | 32 | 162 | 2 | 12 | 162 |
| Q4 | Altruism is the only valid reason for participation in research | 109 | 18 | 49 | 18 | 62 | 100 | 14 | 100 |

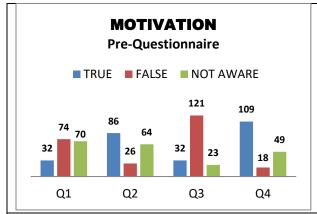


Fig.3 Perceptions regarding the Motivation in prequestionnaire

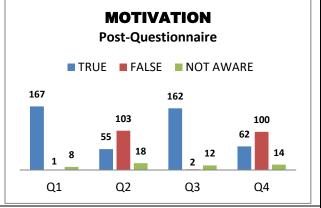


Fig.4 Perceptions regarding the Motivation in postquestionnaire

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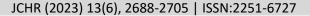




Table-4 Comparison of perceptions regarding the Motivation between pre and post awareness session

| 1 1 0 0 | • |
|-------------------------------------|--------------------|
| Column A | Pre questionnaire |
| vs. | vs. |
| Column B | Post questionnaire |
| | |
| Paired t test | |
| P value | 0.0031 |
| P value summary | ** |
| Significantly different (P < 0.05)? | Yes |
| One- or two-tailed P value? | One-tailed |
| t, df | t=6.898, df=3 |

The pre-questionnaire data on perceptions regarding reasons for engaging in or participating in research revealed, for Q1, 32 participants responded true, 74 responded false and 70 participants responded not aware. Q2, 86 true, 26 and 64 not aware. Q3, 32 true, 121 false and 23 not aware. Q4, 109 true, 18 false and 49 not aware (Table3, Fig. 3). After providing awareness session, responses were: in Q1, 167 true, 1 responded false and 8 not aware. Q2, 55 true, 103 false and 18 not aware. Q3, 162 true, 2 false and 12 not aware. In Q4, 62 participants responded true, 100 responded false and 14 participants responded not aware. (Table3, Fig.4)

Pre Questionnaire data shows, 150 participants scored in between 0 to 1 point out of 4 points, 24 participants had scored between 2 to 3 points, 2 participants had scored

between 4. Post Questionnaire data reveals, 5 participants scored between 0 and 1 out, 111 participants had scored between 2 and 3 points, 60 participants had scored between 4, Which shows that majority of participants improved their clinical research knowledge after awareness session. The individual questions Score in pre-questionnaire shows for Q1, Q2, Q3 and Q4 as 32, 26, 32 and 18 respectively from 176. This reveals that very few participants have the knowledge about clinical research. In the post questionnaire the findings are 167, 103, 162 and 100 respectively and it reflects that there is significant improvement on the knowledge and perception regarding clinical research. The same can be seen on Table 5 which is proving with the P Value 0.0031.

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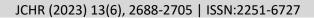




Table-5 Perceptions regarding the Compliance assessment pre and post awareness session

| | | | Pre-Qu | estionnaire | | Post-Questionnaire | | | |
|----|---|------|--------|--------------|-------|--------------------|-------|--------------|-------|
| C | QUESTIONS | TRUE | FALSE | NOT AWARE | SCORE | TRUE | FALSE | NOT AWARE | SCORE |
| Q1 | Volunteers in clinical research get adequate compensation for their participation. | 46 | 119 | 10 | 46 | 173 | 2 | 1 | 173 |
| Q2 | Participants in clinical research get adequate compensation for any adverse outcomes | 32 | 112 | 32 | 32 | 143 | 17 | 16 | 143 |
| Q3 | Confidentiality of research participants is adequately protected. | 44 | 94 | 38 | 44 | 164 | 6 | 6 | 164 |
| Q4 | Volunteers in clinical research get adequate information about the research they participate in | 35 | 107 | 34 | 35 | 164 | 8 | 4 | 164 |
| Q5 | Researchers make sure the maximum safety of research participants | 48 | 92 | 36 | 48 | 148 | 6 | 22 | 148 |
| Q6 | Harmful events occurring during a clinical trial must be due to experimental treatment. | 85 | 35 | 56 | 35 | 6 | 143 | 27 | 143 |

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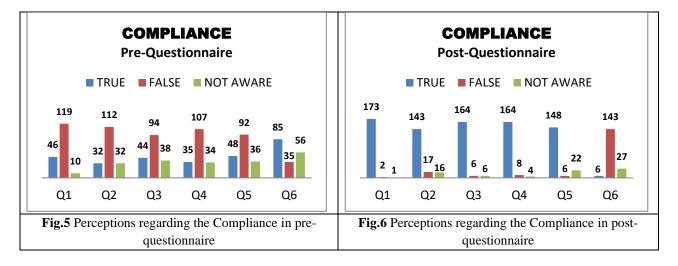


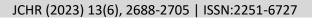
Table-6 Comparison of perceptions regarding the Compliance between pre and post awareness session

| Column A | Pre questionnaire |
|-------------------------------------|--------------------|
| vs. | vs. |
| Column B | Post questionnaire |
| Paired t test | |
| P value | 0.0031 |
| P value summary | ** |
| Significantly different (P < 0.05)? | Yes |
| One- or two-tailed P value? | One-tailed |
| t, df | t=6.898, df=3 |
| | |

On analyzing the pre-questionnaire data to assess their perceptions of the conduct of research, we found Q1, 46 participants provided True, while 119 participants provided False, and 10 participants were not aware. Q2, 32 True, 112 False, and 32 not aware. Q3 showed that 44 True, 94 False and 38 not aware. Q4, 35 true, 107 False and 34 not aware. Q5, 48 true, 92 False and 36 not aware. In Q6, 85 True, 35 False, and 56 not aware (Table 5, Fig. 5). Following providing awareness session, there were notable changes in their perceptions of compliance. In Q1, the vast majority, totaling 173 participants, provided true, while only 2 participants were false, and 1 participant remained unaware. Q2, 143 true, 17 false responses, and 16 unaware. Q3, 164 true, 6 false, and 6 unaware. Q4, 164 true, 8 false and 4 being unaware. Q5, 148 true, 6 false, and 22 unaware. Q6, 6 true, 143 false and 27 unaware. (Table 5, Fig. 6)

Pre questionnaire date resulted, 121 participants scored in between 0 to 1 point out of 6 points, 42 participants had scored between 2 to 4, 13 participants had scored between 5 to 6 points. The post questionnaire data shows, 0 participants scored between 0 and 1 point, 24 participants had scored between 2 and 4 points, 151 participants had scored between 5 and 6 points, which shows that majority of participants improved their clinical research knowledge after awareness session. The individual questions Score in pre-questionnaire shows for Q1, Q2, Q3, Q4, Q5 and Q6 as 46, 32, 44, 35, 48 and 35 respectively from 176. This reveals that very few participants have the knowledge about clinical research. In the post questionnaire the findings are 173, 143, 164, 164, 148 and 143 respectively and it reflects that there is significant improvement on the knowledge and perception

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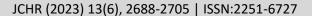
regarding clinical research. The same can be seen on Table 7

which is proving with the P Value 0.0031.

Table-7 Perceptions regarding the Trust assessment pre and post awareness session

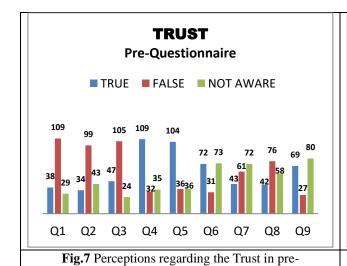
| | | | Pre-Qu | estionnaire | | Post-Questionnaire | | | |
|----|---|------|--------|--------------|-------|--------------------|-------|--------------|-------|
| C | QUESTIONS | TRUE | FALSE | NOT AWARE | SCORE | TRUE | FALSE | NOT AWARE | SCORE |
| Q1 | The government always adequately protects the public against unethical clinical research. | 38 | 109 | 29 | 38 | 160 | 10 | 6 | 160 |
| Q2 | Clinical research information provided by pharmaceutical companies can be trusted | 34 | 99 | 43 | 34 | 164 | 8 | 4 | 164 |
| Q3 | Clinical research information provided by academic institutions can be trusted. | 47 | 105 | 24 | 47 | 148 | 16 | 12 | 148 |
| Q4 | If you decide not to participate in research your doctor will not give you good care. | 109 | 32 | 35 | 32 | 36 | 133 | 7 | 133 |
| Q5 | Doctors force their patients to participate in research. | 104 | 36 | 36 | 36 | 10 | 147 | 19 | 147 |
| Q6 | Human participants in | 72 | 31 | 73 | 31 | 22 | 130 | 24 | 130 |

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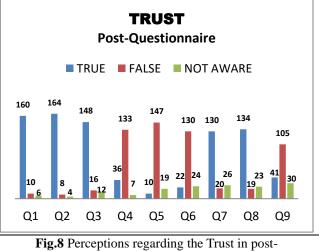




| | clinical | | | | | | | | |
|----|-----------------|----|----|----|----|-----|-----|----|-----|
| | research are | | | | | | | | |
| | treated like | | | | | | | | |
| | experimental | | | | | | | | |
| | animals | | | | | | | | |
| | ('human | | | | | | | | |
| | Guinea Pigs'). | | | | | | | | |
| | Confidentiality | | | | | | | | |
| | is a matter of | | | | | | | | |
| Q7 | importance to | 43 | 61 | 72 | 43 | 130 | 20 | 26 | 130 |
| | research | | | | | | | | |
| | participants. | | | | | | | | |
| | All the results | | | | | | | | |
| | of clinical | | | | | | | | |
| Q8 | research are | 42 | 76 | 58 | 42 | 134 | 19 | 23 | 134 |
| | made available | | | | | | | | |
| | to the public. | | | | | | | | |
| | The media | | | | | | | | |
| | accurately | | | | | | | | |
| Q9 | describes | 69 | 27 | 80 | 27 | 41 | 105 | 30 | 105 |
| | clinical | | | | | | | | |
| | research. | | | | | | | | |



questionnaire



questionnaire

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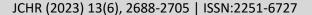




Table-8 Perceptions regarding the Trust between pre and post awareness session

| Column A | Pre questionnaire |
|-------------------------------------|--------------------|
| vs. | vs. |
| Column B | Post questionnaire |
| Paired t test | |
| P value | < 0.0001 |
| P value summary | **** |
| Significantly different (P < 0.05)? | Yes |
| One- or two-tailed P value? | One-tailed |
| t, df | t=18.61, df=8 |

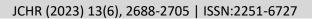
In the assessment of study participant's trust in research, a set of nine questions was administered through a prequestionnaire to participants. The findings revealed in Q1, 38 true, 109 false and 29 unaware. Q2, 34 true, 99 false, 43 not aware. Q3 showed that 47 true, 105 false, 24 not aware, Q4 109 true, 32 false, 35 unaware. Q5, 104 true, 36 false, 36 unaware, Q6, 72 true, 31 false, 73 unaware. Q7, 43 true, 61 false, 72 unaware. Q8, 42 true, 76 false, 58 unaware. And in Q9 69 participants responded true, 27 participants responded false, and 80 were unaware (Table 7, Fig. 7) After providing awareness session, significant changes were observed in their perceptions of compliance. In Q1, 160 participants provided true, while 10 responded false and 6 were unaware. In O2, 164 true, 8 false, and 4 not aware. O3 showed that 148 true, while 16 false, and 12 not aware. Q4, 36 true, 133 false, and 7 unaware. Q5, 10 true, 147 false, 19 unaware. Q6, 22 true, 130 false, 24 unaware. Q7, 130 true, 20 false, and 26 unaware. Q8, 134 true, 19 false, 23 unaware. Q9 41 true, 105 false, and 30 unaware (Table 7, Fig. 8)

In pre questionnaire data, 100 participants scored in between 0 to 1 point out of 9 points, 68 participants had scored between 2 to 7 points, 8 participants had scored between 8 to 9 points. Post Questionnaire data reflects, 0 participants scored in between 0 and 1 point out, 117 participants had scored between 2 to 7 points and 59 participants had scored between 8 to 9 points which shows that majority of participants improved their clinical research knowledge after awareness session. The individual questions Score in prequestionnaire shows for Q1, Q2, Q3, Q4, Q5, Q6, Q7, Q8 and Q9 as 38, 34, 47, 32, 36, 31, 43,42 and 27 respectively from 176. This reveals that very few participants have the knowledge about clinical research. In the post questionnaire the findings are 160, 164, 148, 133, 147, 130, 130, 134 and 105 respectively and it reflects that there is significant improvement on the knowledge and perception regarding clinical research. The same can be seen on Table 9 which is proving with the P Value < 0.0001.

Table-9 Perceptions regarding the Myth assessment pre and post awareness session

| QUESTIONS | | Pre-Questionnaire | | | | | Post-Questionnaire | | | |
|-----------|----------------|-------------------|-------|--------------|-------|------|--------------------|--------------|-------|--|
| | | TRUE | FALSE | NOT AWARE | SCORE | TRUE | FALSE | NOT AWARE | SCORE | |
| Q1 | Clinical Trial | 138 | 32 | 6 | 32 | 9 | 161 | 6 | 161 | |

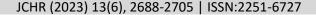
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| | Volunteers are | | | | | | | | |
|----|---|-----|----|-----|----|----|-----|----|-----|
| Q2 | Guinea Pig. Once you decide to participate in a clinical trial you will not able to change your mind. | 80 | 35 | 61 | 35 | 6 | 161 | 9 | 161 |
| Q3 | Being in clinical research is expensive and is not covered by insurance. | 109 | 32 | 35 | 32 | 4 | 152 | 20 | 152 |
| 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 | 28 | 8 | 133 | 35 | 133 |
| Q5 | Clinical trials are always dangerous. | 35 | 24 | 117 | 24 | 25 | 127 | 24 | 127 |
| Q6 | To participate in a clinical trial a person needs to live near the trial site | 108 | 23 | 45 | 23 | 44 | 113 | 19 | 113 |
| Q7 | Only the people who are terminally ill can participate in Clinical trials. | 21 | 28 | 127 | 28 | 18 | 126 | 32 | 126 |
| Q8 | Clinical trials are the last | 13 | 38 | 125 | 38 | 3 | 154 | 19 | 154 |

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| re | sort for cures. | | | | |
|----|-----------------|--|--|--|--|

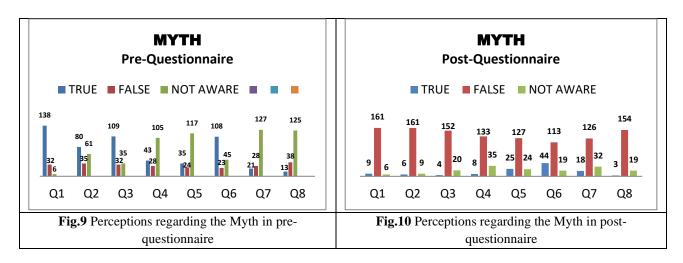


Table-10 Perceptions regarding the Myth between pre and post awareness session

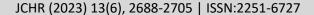
| Column A | Pre questionnaire | | |
|-------------------------------------|--------------------|--|--|
| vs. | vs. | | |
| Column B | Post questionnaire | | |
| Paired t test | | | |
| P value | < 0.0001 | | |
| P value summary | **** | | |
| Significantly different (P < 0.05)? | Yes | | |
| One- or two-tailed P value? | One-tailed | | |
| t, df | t=22.26, df=7 | | |

The pre-questionnaire data for participants, focusing on the evaluation of perceptions regarding myths the findings were, Q1 revealed that 138 participants true, 32 false and 6 unaware. Q2, 80 true, 35 false, and 61 not aware. Q3, 109 true, 32 false, 35 not aware. Q4, 43 true, 28 false, and 105 unaware. Q5, 35 true, 24 false, and 117 unaware. Q6, 108 true, 23 false, and 45 unaware. In Q7, 21 true, 28 false, and 127 unaware. Q8, 13 true, 38 false, and 125 unaware (Table 9, Fig. 9). After engaging in awareness session, notable transformations were observed in their perspectives regarding myths. In the first question (Q1), 9 participants provided true, while 161 responded false and 6 were unaware. Q2, 6 true, 161 false, and 9 not aware. Q3, 4 true,

152 false, and 20 not aware. Q4, 8 true, 133 false, and 35 unaware. Q5, 25 true, 127 false, 24 unaware. Q6, 44 true, 133 false, 19 unaware. Q7, 18 true, 126 false, 32 unaware. Q8, 3 true, 154 false, and 19 unaware (Table 9, Fig. 10).

On Pre questionnaire data, 103 participants scored in between 0 to 1 point out of 8 points, 63 participants had scored between 2 to 6 points and 10 participants had scored between 7 to 8 points. Post questionnaire data resulted, 0 participants scored in between 0 to 1 point, 99 participants had scored between 2 to 6 points and 77 participants had scored between 7 to 8 points. The individual questions Score in pre-questionnaire shows for Q1, Q2, Q3, Q4, Q5, Q6, Q7

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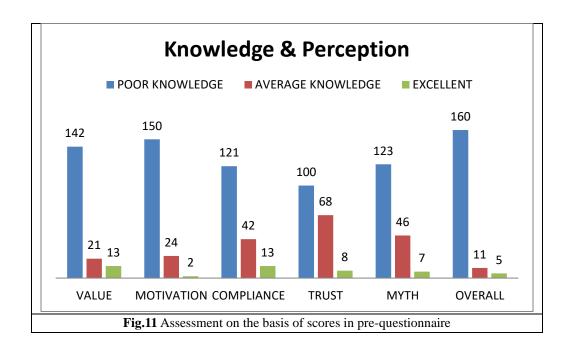


and Q8 as 32, 35, 32, 28, 24, 23, 28 and 38 respectively from 176. This reveals that very few participants have the knowledge about clinical research. In the post questionnaire the findings are 161, 161, 152, 133, 127, 113, 126 and 154

respectively and it reflects that there is significant improvement on the knowledge and perception regarding clinical research. The same can be seen on Table 11 which is proving with the P Value <0.0001.

Table-11 Assessment on the basis of scores

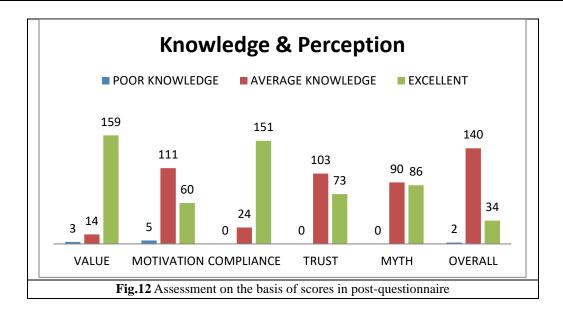
| | Pi | re-Questionnair | e | Post-Questionnaire | | | |
|------------|-----------------------|-----------------|----|-----------------------|----------------------|---------------|--|
| SECTORS | POOR KNOWLE DGE | NOWLE KNOWLED | | POOR KNOWLE DGE | AVERAGE KNOWLEDGE | EXCE LLENT | |
| VALUE | 142 | 21 | 13 | 3 | 14 | 159 | |
| MOTIVATION | 150 | 24 | 2 | 5 | 111 | 60 | |
| COMPLIANCE | 121 | 42 | 13 | 0 | 24 | 151 | |
| TRUST | 100 | 68 | 8 | 0 | 103 | 73 | |
| MYTH | 123 | 46 | 7 | 0 | 90 | 86 | |
| OVERALL | 160 | 11 | 5 | 2 | 140 | 34 | |



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JCHR (2023) 13(6), 2688-2705 | ISSN:2251-6727





The assessment on the basis of scores on five ways of perceptions Value, Motivation, Compliance, Trust And Myth shows that, 160 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 11 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 (Table 11, Fig.11). The result shows that, the majority of participants had no knowledge about the clinical trial in the questionnaire. Post questionnaire reveals that, 2 participants scored in between 0 to 15 point, 140 participants had scored between 16 to 29 points and 34 participants had scored between 30 to 32 points (Table 11, Fig. 12). The result shows that, the majority of participants improved their clinical research knowledge after awareness session.

DISCUSSION

Our study has conducted on 176 participants, the data analysis indicated that a higher percentage of male participants 62.5% (110 individuals), while 37.5% (66 individuals) were female. 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. 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. ¹⁴

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 favorable 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. 15

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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). 16

In our study the assessment of pre-questionnaire was done on the basis of scores on five ways of perceptions Value, Motivation, Compliance, Trust And Myth shows that, 160 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 11 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. In the post-questionnaire 2 participants scored in between 0 to 15 point, 140 participants had scored between 16 to 29 points, only 34 participants had scored between 30 to 32 points. The result shows that, the majority of participants improved their clinical research knowledge after awareness session.

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.¹⁷

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). 18

According to a study done by Rashmi Ashish Kadam et al, 73 investigators from India participated in the survey. The most often encountered problems in subject recruitment were the research protocol's complexity (38%), patients' lack of understanding about clinical trials (37%), and sociocultural concerns connected to trial participation (37%). Approximately 63% of participants agreed that increasing public awareness of clinical trials through the press and media.19 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). 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.²⁰ According to a study done by Supriyo Choudhury et al, 7.5% of the 133 participants

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received targeted instruction on CT and they had a 72.6% favourable opinion towards CTs done in India. However.²¹

CONCLUSION

This study concludes that the common people has very weak knowledge and perception about clinical research and on post questionnaire which improved drastically, which proves that awareness programs has played a crucial role in the enhancement of participants knowledge. There should be proper awareness programs conducted, which will help people understand for the importance of participating in Clinical Research, advancing medical knowledge, and ultimately improving healthcare outcomes.

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.

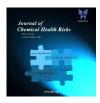
REFERENCES

- [1] Poongothai S, Unnikrishnan R, Balasubramanian J, Nair MD, Mohan V. Why are clinical trials necessary in India? Perspect Clin Res 2014;5:55-9.
- [2] Gogtay NJ, Ravi R, Thatte UM. Regulatory requirements for clinical trials in India: What academicians need to know. Indian J Anaesth 2017;61:192-9.
- [3] Figer BH, Lamture SS, Gandhi T, Chauhan A, Gvalani A, Gogtay NJ, Thatte UM. A survey of knowledge and variables influencing perceptions about clinical research: A cross-sectional study from Mumbai. Perspectives in Clinical Research. 2021 Apr;12(2):93.
- [4] Enderlein G. Pocock SJ: Clinical Trials- a practical approach. John Wiley & Sons. Biometrical Journal. 1985;27 (6):634–634.
- [5] Burns KE, Magyarody N, Jiang D, et al. Attitudes and views of the general public towards research participation. Intern Med J 2013; 43: 531–540.

- [6] Anderson A, Borfitz D, Getz K. Global public attitudes about clinical research and patient experiences with clinical trials. JAMA Network Open. 2018 Oct 5;1(6):e182969.
- [7] Ellis PM, Butow PN. Focus group interviews examining attitudes to randomised trials among breast cancer patients and the general community. Aust N Z J Public Health. 1998;22(5):528–31.
- [8] Asai A, Ohnishi M, Nishigaki E, Sekimoto M, Fukuhara S, Fukui T. Focus group interviews examining attitudes toward medical research among the Japanese: a qualitative study. Bioethics. 2004;18(5):448–70.
- [9] Ahram M, Farkouh AA, Haddad M, Kalaji Z, Yanis A. Knowledge of, attitudes to and participation in clinical trials in Jordan: a population-based survey. Eastern Mediterranean Health Journal. 2020;26(5):539-46.
- [10] Mahaluxmivala N. Human Subject Protection In India–Is It Adequate?. Perspectives in Clinical Research. 2010 Jan;1(1):15.
- [11] Sridharan K, Mehta M, Sivaramakrishnan G. Awareness and attitude of general public about clinical trials from a developing country. American Journal of Experimental and Clinical Research. 2016 Jan;3(1):146-8.
- [12] Ford JG, Howerton MW, Lai GY, et al. Barriers to recruiting underrepresented populations to cancer clinical trials: a systematic review. Cancer. 2008; 112:228–242.
- [13] Leiter A, Diefenbach MA, Doucette J, Oh WK, Galsky MD. Clinical trial awareness: Changes over time and sociodemographic disparities. Clinical Trials. 2015 Jun;12(3):215-23.
- [14] Du W, Mood D, Gadgeel S, Simon MS. An educational video to increase clinical trials enrollment among breast cancer patients. Breast cancer research and treatment. 2009 Sep;117:339-47.
- [15] Awwad O, Maaiah S, Almomani BA. Clinical trials: Predictors of knowledge and attitudes towards participation. International journal of clinical practice. 2021 Mar;75(3):e13687.

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JCHR (2023) 13(6), 2688-2705 | ISSN:2251-6727



- [16] Ghooi RB. Injury and death in clinical trials and compensation: Rule 122 DAB. Perspectives in Clinical Research. 2013 Oct;4(4):199.
- [17] Choi YJ, Beck SH, Kang WY, Yoo S, Kim SY, Lee JS, Burt T, Kim TW. Knowledge and perception about clinical research shapes behavior: face to face survey in Korean General public. Journal of Korean medical science. 2016 May 1;31(5):674-81.F
- [18] Cunningham-Erves J, Mayo-Gamble TL, Hull PC, Lu T, Barajas C, McAfee CR, Sanderson M, Canedo JR, Beard K, Wilkins CH. A pilot study of a culturally-appropriate, educational intervention to increase participation in cancer clinical trials among African Americans and Latinos. Cancer Causes & Control. 2021 Sep;32(9):953-63.
- [19] Chu SH, Kim EJ, Jeong SH, Park GL. Factors associated with willingness to participate in clinical trials: a nationwide survey study. BMC Public Health. 2015 Dec;15(1):1-8.
- [20] Kadam RA, Borde SU, Madas SA, Salvi SS, Limaye SS. Challenges in recruitment and retention of clinical trial subjects. Perspectives in clinical research. 2016 Jul;7(3):137.
- [21] Choudhury S, Pradhan R, Dubey L, Barman L, Biswas T, Das M, Chatterjee S. Knowledge and perception regarding clinical trials among doctors of government medical colleges: A questionnaire-based study. Perspectives in clinical research. 2016 Apr;7(2):94.