



Knowledge, Attitude, and Perception of Clinical Trials among Cancer Patients in India: A Single-Center Cross-Sectional Study

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Ind J Med Paediatr Oncol 2026;47:311–320.

Abstract

Introduction Cancer is the leading cause of death globally and its incidence keeps increasing annually. Clinical trials (CTs) hold massive prospects to benefit patients, optimize treatment strategies, and improve evidence-based medical practice.

Objectives To assess the present levels of knowledge, attitude, and perception of CTs among cancer patients.

Materials and Methods A cross-sectional study was conducted in the tertiary care center among cancer patients using a standardized self-administered questionnaire consisting of the domains—demographics, knowledge, attitude, and perception.

Results A total of 679 cancer patients were invited to participate in the survey. Of these, 375 ($n=375$) answered “yes” to the screening question and went on to complete the remaining 15 questions, which evaluated their knowledge, attitudes, and perceptions of CTs. This resulted in a final sample size of 375 participants, reflecting that 55.2% had an understanding of CTs. A total of 311 (82.9%) patients recognized that CT participation is voluntary. Additionally, 307 (81.9%) participants were open to the idea of engaging in CT if required in the future, whereas 290 (77.3%) were apprehensive of the potential risks that may be associated with the CT.

Conclusion The study provides valuable insights into the factors that affect the understanding of CTs among cancer patients and highlights the positive attitude and perception, while significant gaps remain in awareness and actual participation, along with the understanding of the ethical conduct of CTs. Targeted educational initiatives, physician involvement, community-based advocacy, and culturally focused communication strategies are essential to bridge these gaps.

Keywords

- clinical trial
- attitude
- awareness
- knowledge
- cancer patients
- trial participation

Introduction

Cancer is the leading cause of death globally, and its incidence keeps increasing annually. In 2022, it was estimated that over half of all cases (49.23%) and the majority of cancer deaths worldwide (56.2%) will occur in Asia, home to 59.2% of the world's population. According to GLOBOCAN (a database

for global cancer burden), India ranks third for cancer incidence in 2020, behind China and the United States. Moreover, it also projected a 57.5% increase between 2020 and 2040. The disproportionately greater cancer mortality burden compared to the corresponding incidence burden in Asian and African countries indicates the late stage of diagnosis.¹ Enrollment in a clinical trial (CT) is recommended for all

article published online
June 17, 2026

DOI <https://doi.org/10.1055/s-0046-1824463>.
ISSN 0971-5851.

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eligible cancer patients who are either progressing or for whom there are no alternatives to standard-of-care treatment, as CTs are regarded as the pinnacle of research methodology when assessing the safety and efficacy of health care interventions. CT holds massive prospects to benefit patients, optimize treatment strategies, and improve evidence-based medical practice.^{2,3} The National Comprehensive Cancer Network states that “clinical research is the best treatment for any cancer patient.”^{4,5} Over the past decade, India has emerged as one of the main hubs for the conduct of clinical research.⁶ As per the Clinical Trial Registry of India (CTRI) database as of May 5, 2024, 66,777 trials have been registered. However, the effectiveness of these trials heavily relies on the active participation and comprehension of the enrolled patients, as CT participants are the key to contributing to the researcher’s knowledge regarding cancer and also help in the development of cancer treatment options.^{7,8} Poor enrollment in CT results not only in the delay of trial completion but also hampers the approval of more effective novel treatments for cancer patients. Various factors affect the patient’s knowledge, attitude, and perception about CTs, which eventually affect the patient’s recruitment and retention in CTs, and this, being the critical step in determining the success of CT, has also become the most challenging aspect of CT in recent times.^{9–12} Therefore, the present study aims to address the knowledge, attitude, and perception of CT among cancer patients; this could potentially be of value to oncologists to recruit and retain participants in CTs, improve patient education strategies, thereby enhancing the efficacy of CTs.

Materials and Methods

Study Design

The single-center cross-sectional study was conducted at a tertiary care center in the southern region of India, between August 2024 and October 2024. The Institutional Ethics Committee granted ethical approval. Written informed consent was obtained from cancer patients who met the inclusion and exclusion criteria and were invited to participate in the study. The study focused on Indian patients aged 18 to 80 years who had been diagnosed with cancer and had received either medical or surgical intervention or supportive care for cancer for at least 3 months and were clinically capable of completing the survey. The patients with known psychiatric illnesses, those who declined to participate, as well as individuals currently enrolled in a CT or who had completed a trial, were excluded from the study.

Questionnaire

A standardized self-administered questionnaire was developed with input from experts in their field and based on extensive literature reviews of similar questionnaires. The questionnaire was developed in English and later translated into Tamil and Telugu by bilingual experts. The questionnaire was administered in the participant’s preferred language (English/Tamil/Telugu) and was given adequate time to answer, after the investigators explained the contents of the questionnaire. Any of the study team members will

verbally read out the questionnaire to assist the illiterate participants in completing it. The questionnaire consists of four parts, of which the first contains the patient’s demographic details such as age, gender, locality, education, occupation, and their diagnosis and the year of diagnosis. The next three sections of the questionnaire each consist of five questions on the domains of knowledge (K1–K5), attitude (A1–A5), and perception (P1–P5), along with an initial screening question, resulting in a total of 16 questions. If the response is “no” to the screening question, the subsequent questions become inapplicable. The questions were formatted as Yes or No, so participants indicated their responses by ticking the corresponding boxes.

Inclusion and Exclusion Criteria

Inclusion criteria include male or female cancer patients, aged between 18 and 80 years, diagnosed with any cancer and have received either medical or surgical intervention or supportive care for cancer for at least 3 months, and at any stage of cancer disease with any comorbidities.

Exclusion criteria include pediatric patients (age less than 18 years), patients with any known psychiatric illnesses, patients currently enrolled in or end of trial patients in one or more CTs of any phase approved by the Institute Ethics Committee (IEC), Cancer Institute (WIA), and participants withdrawn from the study based on the principal investigator or coinvestigator’s discretion.

Primary and Secondary Outcome

The primary outcome is to elicit the participant’s willingness to participate in a CT and advocate it to others and the secondary outcome is to assess the knowledge, attitude, and perception of CTs among cancer patients and to evaluate the factors that positively influenced the patient’s willingness to partake in CTs and the barriers to participation.

Results

Statistical Analysis

The statistical analysis was primarily descriptive, with the results presented as percentages. A chi-square test was used to assess the relationship between the participants’ knowledge, attitude, and perception with the categorical variants (age, gender, education, locality, and cancer diagnosis). It was not statistically significant, as $p < 0.05$ were considered statistically significant.

Ethical Approval

The study was approved by the Institutional Ethics Committee, Cancer Institute, WIA, with the study reference number IEC/2024/July 11 on July 26, 2024. All our study procedures adhered to the Declaration of Helsinki.

Results

The screening question asked was: “Do you understand what CTs (research studies) are?” Over the 3-month study period, 679 cancer patients were invited to participate in the survey.

Of these, 375 ($n=375$) answered “yes” to the screening question and went on to complete the remaining 15 questions, which evaluated their knowledge, attitudes, and perceptions of CTs. This resulted in a final sample size of 375 participants, reflecting that 55.2% had an understanding of CTs. Of 375 participants, the majority filled the questionnaire in Tamil (363), followed by English (10) and Telugu (3).

The median age of the study population was found to be 49 years (range: 18–80) with the interquartile range of 16 years, ranging from $Q1=41$ to $Q3=57$ years. There were 239 (63.73%) females and 136 (36.27%) males. It was found that 170 (45.3%) belonged to the urban population. Most of the study population had a school education—elementary school 130 (34.67%), secondary school 84 (22.4%), and high school 61 (16.27%). They were followed by 71 (18.9%) undergraduates and 27 (7.2%) postgraduates and above (►Table 1).

A total of 304 (44.8%) of the participants had answered “no” to the screening question. Within this group, a higher proportion were elderly (48%), females (70.1%), and individuals from rural areas (70.4%), indicating potential disparities

in awareness and access to information regarding clinical research.

Overall, 301 (80.3%) participants were aware of the potential benefits a CT could offer, and 288 (76.8%) knew that CTs had protocols to ensure patient safety. However, only 293 (63.7%) participants were aware of the ethics committee that governs and monitors CT and safeguards participants' welfare and rights, while 311 (82.9%) patients recognized that CT participation is voluntary (►Table 2).

The participant's attitude regarding CT was mostly positive, nearly 371 (98.9%) believed CT contributes to medical achievements and 363 (96.8%) thought that the government should support CT and research through the provision of resources and awareness initiatives. Additionally, 307 (81.9%) participants were open to the idea of engaging in CT if required in the future, whereas 290 (77.3%) were apprehensive of the potential risks that may be associated with the CT (►Table 2).

A total of 335 (89.3%) expressed that they would recommend their family/friends to participate in CT if suggested by the health care provider, signifying the importance of the role of the physician in CT advocacy. Only 236 (62.9%) had encountered CT through media resources, such as newspapers/magazines or other online platforms, and merely 95 (25.3%) had sought CT for their condition, suggesting the need for more widespread dissemination of information on clinical research by using multimedia resources. Only 25.3% personally sought CTs, while a high proportion of participants reported familiarity with CT participation, which reflects perceived or indirect awareness, indicating a gap between awareness and true engagement (►Table 2).

The chi-square test was used to assess the relationship between the participant's knowledge, attitude, and perception with categorical variants (age, gender, education, locality, and cancer diagnosis). It was not statistically significant, as $p < 0.05$ were considered statistically significant (►Tables 3–7).

Discussion

The study was intended to assess the knowledge, attitude, and perception of CTs among cancer patients in a single tertiary care center in India. The study results reveal valuable perspectives on how cancer patients regard and comprehend CTs and research.

The findings exhibit encouraging levels of awareness and positivity toward CT, although a gap exists in the understanding of the role of the ethics committee and informed consent protocols, which need to be bridged.

A total of 301 (80.3%) were aware of the potential benefits of CT in our study, comparable to the 85.9% as per the study by Al-Tannir et al, conducted in Saudi Arabia.¹³ Similarly, 311 (82.9%) participants acknowledged that participation in CT should be voluntary, which closely aligns with the 72.4% reported by Al Tannir et al and is further supported by the study by Biswakarma et al of Delhi, where 94.72% participants agreed that prior to the CT enrollment, the patient's willingness must be sought, emphasizing the voluntary participation in a CT.¹⁴ Regarding the knowledge of the informed

Table 1 Demographics

	Number (N)	Percentage (%)
Age (y)		
18–25	16	4.2
26–35	30	8.0
36–50	162	43.2
> 50	167	44.5
Gender		
Male	136	36.3
Female	239	63.7
Education		
Illiterate	2	0.5
Elementary school	130	34.7
Secondary school	84	22.4
High school	61	16.3
Undergraduate	71	18.9
Postgraduate	27	7.2
Occupation		
Skilled	56	14.9
Semiskilled	111	29.6
Unskilled	208	55.5
Urban/rural		
Urban	170	45.3
Rural	205	54.7
Years of diagnosis		
< 1	151	40.3
1–5	162	43.2
> 5	62	16.5

Table 2 Knowledge, attitude, and perception of the participant's toward clinical trials

		Yes (%)	No (%)
Knowledge			
K1	Are you aware of the potential benefits of participating in a research (clinical trial)?	80.3	19.7
K2	Do you know that there are protocols to ensure patient safety in research (clinical trials)?	76.8	23.2
K3	Do you know that participation in research (clinical trials) is voluntary?	82.9	17.7
K4	Do you know that you have to sign an informed consent before participating in a clinical trial?	79.2	20.8
K5	Do you know that there is a body called an ethics committee monitoring research and protecting patients in clinical trials?	63.7	36.3
Attitude			
A1	Do you believe that participating in clinical trials contributes to medical advancements?	98.9	1.1
A2	Are you open to the idea of participating in a clinical trial in the future?	81.9	18.1
A3	Do you feel participating in a clinical trial will potentially benefit your own health?	94	59
A4	Are you concerned about the potential risks that may be associated with clinical trials?	77.3	22.7
A5	Do you think the government should encourage clinical trials/research and provide more resources for conducting research?	96.8	3.2
Perception			
P1	Have you ever sought clinical trials/research for your condition?	25.3	74.7
P2	Did you discuss clinical trials/research options with your doctor?	70.1	29.9
P3	Have you read about clinical trials (research) in newspapers/magazines/on the internet, or other media?	62.9	37.1
P4	Do you know anyone in your community who has participated in a clinical trial?	96.3	3.7
P5	If required, would you recommend others (relatives/friends) to participate in clinical trials if his/her doctor suggests?	89.3	10.7

Table 3 Knowledge, attitude, and perception score across age groups

Age	Response	18–25 y	26–35 y	36–50 y	>50 y	Chi-square (p-value)
Question						
K1	Yes	10	26	131	134	0.261
	No	6	4	31	33	
K2	Yes	14	27	126	121	0.120
	No	2	3	36	46	
K3	Yes	12	27	138	134	0.361
	No	4	3	24	33	
K4	Yes	12	26	131	128	0.548
	No	4	4	31	39	
K5	Yes	6	15	54	61	0.381
	No	10	15	108	106	
A1	Yes	15	29	161	166	0.102
	No	1	1	1	1	
A2	Yes	14	23	142	128	0.055
	No	2	7	20	39	
A3	Yes	14	28	151	160	0.492
	No	2	2	11	7	

Table 3 (Continued)

Age	Response	18–25 y	26–35 y	36–50 y	>50 y	Chi-square (<i>p</i> -value)
Question						
A4	Yes	12	24	127	127	0.933
	No	4	6	35	40	
A5	Yes	15	29	158	161	0.839
	No	1	1	4	6	
P1	Yes	4	9	41	41	0.940
	No	12	21	121	126	
P2	Yes	10	18	110	125	0.253
	No	6	12	52	42	
P3	Yes	11	24	101	100	0.198
	No	5	6	61	67	
P4	Yes	1	1	6	6	0.959
	No	15	29	156	161	
P5	Yes	15	25	150	145	0.224
	No	1	5	12	22	

Table 4 Knowledge, attitude, and perception score across gender

Gender	Response	Male	Female	Chi-square (<i>p</i> -value)
Question				
K1	Yes	102	199	0.053
	No	34	40	
K2	Yes	110	178	0.158
	No	26	61	
K3	Yes	109	202	0.204
	No	27	37	
K4	Yes	103	194	0.212
	No	33	45	
K5	Yes	46	90	0.458
	No	90	149	
A1	Yes	135	236	0.637
	No	1	3	
A2	Yes	118	189	0.063
	No	18	50	
A3	Yes	125	228	0.167
	No	11	11	
A4	Yes	104	186	0.763
	No	32	53	
A5	Yes	130	233	0.314
	No	6	6	
P1	Yes	36	59	0.702
	No	100	180	

(Continued)

Table 4 (Continued)

Gender	Response	Male	Female	Chi-square (p-value)
Question				
P2	Yes	93	170	0.576
	No	43	69	
P3	Yes	78	158	0.091
	No	58	81	
P4	Yes	5	9	0.965
	No	131	230	
P5	Yes	121	214	0.864
	No	15	25	

Table 5 Knowledge, attitude, and perception score across years of diagnosis

Years of diagnosis	Response	>5 y	1–5 y	<1 y	Chi-square (p-value)
Question					
K1	Yes	47	134	120	0.484
	No	15	28	31	
K2	Yes	49	123	116	0.886
	No	13	39	35	
K3	Yes	46	139	126	0.116
	No	16	23	25	
K4	Yes	44	133	120	0.184
	No	18	29	31	
K5	Yes	20	59	57	0.750
	No	42	103	94	
A1	Yes	61	160	150	0.797
	No	1	2	1	
A2	Yes	49	137	121	0.487
	No	13	25	30	
A3	Yes	59	152	142	0.928
	No	3	10	9	
A4	Yes	46	132	112	0.247
	No	16	30	39	
A5	Yes	59	159	145	0.411
	No	3	3	6	
P1	Yes	20	42	33	0.277
	No	42	120	118	
P2	Yes	39	113	111	0.304
	No	23	49	40	
P3	Yes	36	111	89	0.147
	No	26	51	62	
P4	Yes	1	7	6	0.620
	No	61	155	145	
P5	Yes	57	142	136	0.605
	No	5	20	15	

Table 6 Knowledge, attitude, and perception score across locality

Locality	Response	Urban	Rural	Chi-square (<i>p</i> -value)
Question				
K1	Yes	139	162	0.507
	No	31	43	
K2	Yes	136	152	0.181
	No	34	53	
K3	Yes	139	172	0.584
	No	31	33	
K4	Yes	137	160	0.546
	No	33	45	
K5	Yes	64	72	0.613
	No	106	133	
A1	Yes	168	203	0.851
	No	2	2	
A2	Yes	133	174	0.096
	No	37	31	
A3	Yes	160	193	0.989
	No	10	12	
A4	Yes	135	155	0.381
	No	35	50	
A5	Yes	167	196	0.150
	No	3	9	
P1	Yes	45	50	0.645
	No	125	155	
P2	Yes	121	142	0.688
	No	49	63	
P3	Yes	113	123	0.196
	No	57	82	
P4	Yes	8	6	0.366
	No	162	199	
P5	Yes	147	188	0.102
	No	23	17	

Table 7 Knowledge, attitude, and perception score across education levels

Education	Response	Below 12th	Undergraduate	Postgraduate	Chi-square (<i>p</i> -value)
Question					
K1	Yes	216	63	22	0.125
	No	61	8	5	
K2	Yes	205	58	25	0.051
	No	72	13	2	
K3	Yes	226	61	24	0.478
	No	51	10	3	
K4	Yes	217	56	24	0.434
	No	60	15	3	

(Continued)

Table 7 (Continued)

Education	Response	Below 12th	Undergraduate	Postgraduate	Chi-square (p-value)
Question					
K5	Yes	93	29	14	0.114
	No	184	42	13	
A1	Yes	276	69	26	0.076
	No	1	2	1	
A2	Yes	231	58	18	0.098
	No	46	13	9	
A3	Yes	262	66	25	0.820
	No	15	5	2	
A4	Yes	216	52	22	0.604
	No	61	19	5	
A5	Yes	269	69	25	0.435
	No	8	2	2	
P1	Yes	62	24	9	0.087
	No	215	47	18	
P2	Yes	201	42	20	0.079
	No	76	29	7	
P3	Yes	166	49	21	0.093
	No	111	22	6	
P4	Yes	8	4	2	0.320
	No	269	67	25	
P5	Yes	251	61	23	0.399
	No	26	10	4	

consent process in our study, it was around 297 (80%) participants, closely reflecting the finding of 76% by Biswarkarma et al. Al-Tannir et al reported that the knowledge regarding essential elements of informed consent ranges from 55.7 to 85.7%. But the knowledge regarding the placement of protocols to ensure patient safety and the presence of the ethics committee to monitor the research process and to protect patients in CTs was comparatively less, with 288 (76%) and 239 (63.7%), respectively, and this is crucial for ethical understanding and the trust in the governance. This is similar across different populations, as 48.7 and 79% of the participants believed that CTs are conducted ethically as per Al-Tannir et al and Balasubramanian et al, respectively.^{13–15} With the COVID-19 pandemic catalyzing a global shift in public interest in medical research and CT leading to an improved visibility and accreditation, including in the low- and middle-income countries, it is important to address this issue to promote recruitment and retention in the CT.^{16,17} As earlier literatures suggest with the understanding of the safety of trials significantly increases the patient's willingness to take part in a trial. The knowledge gap regarding the regulatory and ethical domains reflecting improved regulatory transparency highlights the need for improved patient education strategies as recommended by Pandey et al in their review

of the CTRL, which plays a critical role in promoting accountability and patient safety.^{4,5}

The participant's attitude toward CT was generally positive, with the majority believing that it would contribute to medical advancements, potentially benefit the patient's health, and highlight the necessity for the government to encourage, support, and provide resources toward medical research/CTs. Despite the favorable outlook, 290 (77.3%) also believe that potential risk may be associated with CT. Several studies largely reflect this.

Factors facilitating include perceived personal health benefits, altruism, financial incentives, trust in physicians, understanding of CT, and motivation and effective engagement of the participants. Conversely, the barriers include mistrust in trial organizations, concerns regarding the efficacy and safety of investigational treatment, apprehension about loss of confidentiality, logistical challenges and dependence on others, as well as language limitations and psychological hesitations.¹⁸ These underscore the cognitive, sociocultural, and emotional factors that play a role in deciding the willingness of the patient's participation in CTs, highlighting the need for culturally sensitive, trust-building, and participant-centered recruitment strategies.

Nevertheless, 307 (81%) participants were willing to participate in future CT, expressing high enrollment

opportunities if appropriate information is made available, as only 95 (25%) had sought CT for their own condition, reflecting the gap between positive attitude and personal action, as noted by previous studies where many patients expressed interest in clinical research but was deterred by limited opportunities, knowledge, and resources.^{8,10} Therefore, with appropriate physician guidance, clear communication, and culturally tailored patient education, we could translate these positive attitudes into greater CT participation.

Almost 112 (70%) participants had discussed CTs with their physicians, highlighting the importance of clinician-initiated conversations, which aligns with the study by Sateren et al emphasizing that higher accrual is associated with health care providers support and institutional encouragement.¹¹ A total of 236 (62%) patients had encountered medical research via media exposure, such as newspapers/magazines/internet, indicating community exposure through mass media, which can further be utilized to clarify misconceptions regarding clinical research and to raise awareness, as well as harness it as a motivational tool to enhance recruitment.¹⁸

Additionally, peer influence has also emerged as a pivotal factor to promote trust and support openness toward clinical research. Prior studies suggest that peer networks and shared experiences can enhance confidence and acceptance of trial participation.¹⁸ This underscores the potential of community-driven strategies such as patient testimonials and peer advocacy to complement institutional efforts for better recruitment, retention, and engagement for the participants.

The study gives valuable insights into the understanding of CTs using a structured questionnaire (including regional language), and a larger sample size could be beneficial for future considerations of factors that could contribute to or impede the planning, development, and implementation of CTs in the cohort of oncology patients, and also to improve the strategies to curb the barriers for CT enrollment and retention. The key limitation of the study is that confining the analysis to participants who responded yes to the screening question may have led to selection bias, potentially overestimating the participants knowledge, attitude, and willingness toward CT and also the questionnaire was tested among a small group of patients to assess clarity, informally; however, no formal pilot testing was performed. It is a cross-sectional design, henceforth subject to bias, as well as being single-center, the findings could not be generalized to other regions or health care settings.

Conclusion

The study provides valuable insights into the factors that affect the knowledge, attitude, and understanding of CTs among cancer patients, as there are limited data regarding this in India and highlights the positive attitude and perception, while significant gaps remain in awareness and actual participation, along with the understanding of the ethical conduct of CTs. Targeted educational initiatives, physician involvement, community-based advocacy, and culturally focused communication strategies are essential to bridge

these gaps and to enhance CT enrollment and ensure ethical and effective clinical research to promote the platform of clinical research in the field of oncology in India, to contribute to further advancements.

Patient Consent

Written informed consent was obtained.

Conflict of Interest

None declared.

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