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ORIGINAL RESEARCH

Impact of COVID-19 on Public Knowledge and Attitudes Toward Participating in Clinical Trials in Saudi Arabia: A Cross-Sectional Study

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Correspondence: Abdulhadi M Alqahtani Research Center, Clinical Research Department, King Fahad Medical City, Riyadh City, Saudi Arabia Email ph.abdalhadi@gmail.com **Objective:** We aimed to evaluate the impact of the COVID-19 pandemic on the knowledge and attitudes of patients among the Saudi population toward participating in clinical trials. **Methods:** We conducted a descriptive, cross-sectional analysis using self-administered questionnaires for patients who attended the outpatient clinics at King Fahad Medical City and King Saud University Medical City in Riyadh, Saudi Arabia. The questionnaires included general questions about sociodemographic information, patient knowledge about clinical trials, and patient attitudes toward clinical trial participation. We used descriptive analysis to evaluate the impact of COVID-19 on patient knowledge and attitudes about

Results: From November 2019 to October 2020, 822 responses were collected from participants in two medical cities and included in the analysis. Most of the study participants (81%) were younger than age 42 years. Our findings showed no difference between participants who participated in clinical trials before versus during the COVID-19 pandemic (P = 0.129).

Conclusion: The Saudi population knows about clinical trials, but they lack knowledge about the role of the ethics committee and about informed consent. Also, most of them do not have the experience of participating in a clinical trial. Still, they have moderately positive attitudes toward clinical trials.

Keywords: knowledge, attitude, clinical trials, COVID-19, Saudi Arabia

Introduction

clinical trials.

Clinical studies are medical experiments aimed at determining the results of patient health when they are participating in the study.¹ Depending on the type of study, patients in clinical trials can receive specific treatments. Clinical trial results may provide new information or techniques that can broaden medical knowledge for treatment or diagnostic purposes.²

Participation and enrollment of patients in clinical trials is one of the leading challenges faced by researchers. In 2020, Jin et al published a systematic review to investigate factors affecting people participation in clinical trials.³ The results included 63 studies from various countries and settings. The leading factor affecting participation is the level of trust in research entity and the researcher. Safety issues, include adverse drug reactions, were also perceived as an important factor. In addition, educational level might affect public attitude, studies have found that people with biomedical degrees are more willing to participate compared with other

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groups. As for gender and age, young people and men are more willing to participate compared with older adults and women. Finally, having a previous good experience with clinical trials will enhance the chance of future participation.

From this systematic review, there is a wide array of factors that affect people attitude toward participation in clinical trials. Efforts to enhance the trust in research institutions and researcher and utilizing mass media to reflect on successful experiences might further enhance participation in clinical research.

A multicenter study conducted in some Middle Eastern countries, including Egypt, the Kingdom of Saudi Arabia, and Jordan, showed that approximately 50% of study participants had positive attitudes toward participation in COVID-19 trials.⁴ The main factors that influenced public willingness to participate were the ethical conduct of the clinical trials and the desire to protect family members from COVID-19 from accelerating the return to normal life.

From this study, it was clear that people in the Middle East, including Saudi Arabia, are generally receptive to participation in clinical trials. However, the magnitude of change in perception compared with pre-pandemic levels was not measured.

Therefore, we aimed to update the literature about the main factors affecting public decisions to participate in a clinical trial. During the COVID-19 pandemic, we observed huge awareness campaigns through social media to increase knowledge about clinical trials and change public attitudes toward participating in clinical trials. Therefore, we assumed that knowledge and attitudes could change during the COVID-19 pandemic, and we assessed the impact of COVID-19 on the Saudi public's perception of clinical trials and knowledge about clinical trial participation.

Methods

Study Design/Setting

We conducted a descriptive, cross-sectional analysis using self-administered questionnaires in both Arabic and English languages. The study took place at KFMC and King Saud University Medical City (KSUMC) in Riyadh, Saudi Arabia. The data were collected between November 2019 and October 2020.

Inclusion and Exclusion Criteria

Using a convenience sampling approach, we invited patients who attended outpatient clinics to participate.

Eligible participants were at least 18 years old and knew the term "clinical trial." Patients who had abnormal mental health, an acute psychiatric emergency, or a critical illness were excluded.

Questionnaire Development

Previous studies similar to ours were reviewed to identify possible factors affecting patient knowledge of and attitudes toward participating in clinical trials.^{5–7} Our questionnaire was then modified to fit the study's aim.

The questionnaire consisted of 43 questions, which were classified into three sections. The first section consisted of questions about sociodemographic characteristics, such as age, gender, marital status, residential area, number of children (if any), educational level, educational background, reason for the visit, level of health insurance (if any), and regular source of care (if any). The second section evaluated the patient's knowledge about clinical trials (six questions). Finally, the last section involved questions about the patient's attitude toward clinical trials (27 questions).

A pilot study was carried out among 10 patients at KFMC to ensure good reliability; Cronbach's alpha was 0.88, indicating the reliability of our tool, and no substantive changes were made to the questionnaire after the pilot study. We classified the knowledge question (ie, section 2) responses into "yes" and "no" groups. The attitude domain was assessed using a Likert scale (strongly disagree, disagree, neutral, agree, and strongly agree).

Data Collection

The questionnaire was administered electronically using Google Forms to facilitate data collection, tracking, and validation. The questionnaire responses were collected by volunteers. The volunteers had medical backgrounds (eg, student or graduate student in medical fields), and four volunteers had access to the questionnaire and collected the data.

Sample Size

Our sample size was determined by the number of patients visiting outpatient clinics in KFMC and KSUMC. Overall, 14,736 people visited the outpatient clinics at these two locations. Using that number and the OpenEpi website,⁸ we calculated our necessary sample size to achieve a P value of 0.05 as 375 participants.

Statistical Analysis

Data analysis was performed using SPSS 25.0 software (SPSS Inc., Chicago, IL, USA). We used a descriptive-frequency test and the chi-square test to determine the intensity of the correlation between independent variables (age, gender, educational level, and marital status) and the major outcome variable of attention. To improve our analyses, we classified education levels into subgroups of uneducated, elementary school, middle/high school, bachelor's degree, master's degree, and doctorate degree.

Ethical Considerations Procedure

This study was conducted in accordance with the Declaration of Helsinki. Permission to conduct this

study was obtained from the institutional review board at KFMC (project No. 19-516) and the ethical committee at KSUMC (project No. E-194380). Electronic informed consent was provided by each participant before they answered the questionnaire. Participants did not receive any compensation for participation in the study.

Results

From November 2019 to October 2020, 822 responses from participants in two medical cities were reported and included in the analysis. We aimed to identify and determine the main barriers that affect patient participation in clinical trials in Saudi Arabia.

Table I Sociodemographic Information	۱
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		Total			COVID 9 lemic	During Pano	P-value	
		n	%	n	%	n	%	
Age	18–30	388	47.2	169	20.6	219	26.6	0.5
	31-42	286	34.8	130	15.8	156	19.0	
	43–54	104	12.7	53	6.4	51	6.20	
	>54	44	5.4	17	2.1	27	3.3	
Gender	Male	337	41.0	154	18.7	183	22.3	0.7
	Female	485	59.0	215	26.2	270	32.9	
Marital status	Single	310	37.7	135	16.4	175	21.3	0.6
	Married	512	62.3	234	28.5	278	33.8	
Having children	Yes	413	50.2	190	23.1	223	27.1	0.5
	No	409	49.8	179	21.8	230	28.0	
Residential area	Village	75	9.1	33	4.0	42	5.1	0.9
	City	747	90.9	336	40.9	411	50.0	
Educational level	Uneducated	3	8.2	I	2.7	2	5.5	0.3
	Elementary school	16	1.9	10	1.2	6	0.7	
	Middle/high school	227	27.6	93	11.3	134	16.3	
	Bachelor's degree	492	59.9	233	28.4	259	31.5	
	Master's degree	69	8.4	27	3.3	42	5.1	
	PhD's degree	15	1.8	5	0.6	10	1.2	
Educational background	Non- medical field	469	57.1	221	26.9	248	30.2	0.6
	Medical field	120	14.6	53	6.5	67	8.2	
Reason of the visit	Treatment	287	34.9	134	16.3	153	18.6	0.5
	Follow-up	535	65.I	235	28.6	300	36.5	
Regular source of care	Government hospitals	624	75.9	283	34.4	341	41.5	0.6
	Private hospitals	198	24.1	86	10.5	112	13.6	
Health insurance	Yes	224	27.3	99	12.0	125	15.2	0.8
	No	598	72.8	270	32.9	328	39.9	

Most study participants (47.2%) were between 18 and 30 years old. There was no significant difference between participant ages before versus during the pandemic. In our sample, 59% of participants were women. Overall, 37.7% of participants were single and 62.3% were married; 50.2% of married participants had children. Most participants lived in the city (90.9%), had a bachelor's degree (59.9%), and had a nonmedical background (57.1%). In addition, 24.1% of patients were treated at a private hospital, but the majority (75.9%) received their regular care at governmental hospitals (75.9%); overall, 72.8% of participants had no health insurance (Table 1).

As shown in Table 2, no differences existed between the number of participants who participated in clinical trials before versus during the COVID-19 pandemic (P = 0.129). Also, regarding patient knowledge about clinical trials, most patients (67.2%) had poor knowledge about the ethics committee in general before the pandemic, but knowledge increased significantly (P = 0.02) during the COVID-19 pandemic.

Unfortunately, most patients (75.3%) had poor knowledge about whom to contact for problems or adverse events during the clinical trial. This knowledge increased during the pandemic by 4.9%. A significant difference existed in participant trust of physicians (P = 0.08); 88.1% of participants believed that their physicians could not start a clinical trial without professional approval to protect patients. (Table 2).

 Table 2 The Knowledge About Participating in Clinical Trials

Survey Item Before Total During P-value COVIDI9 COVID19 Pandemic Pandemic n % n % n % 8.2 4.38 Have you been involved in clinical trials before? 67 36 31 3.8 0.1 Yes 755 91.9 422 No 333 40.5 51.3 Do you think Clinical trials are only used as a last resort? Yes 326 39.7 160 19.5 166 20.2 0.1 496 60.3 209 25.4 287 35.0 No 270 32.9 105 12.8 165 20.1 0.02 Do you know about the Ethics committee before? Yes 288 No 552 67.2 264 32.I 35.04 14.8 203 24.7 81 9.9 122 Do you know whom to contact if you have a problem like an adverse event and Yes 0.1 serious adverse event in a clinical trial? No 619 75.3 288 35.04 331 40.3 98 11.9 5.6 0.08 Do you think the physician can start a clinical trial without the approval of Yes 52 6.3 46 88. I professionals who protect patient rights? No 724 317 38.6 407 49.5 Do you know about "Informed consent"? Yes 308 37.5 136 16.6 172 21.0 0.7 No 514 62.5 233 28.4 281 34.2

In Table 3 shown the participant attitudinal fear from participating in a clinical trial before and during the COVID19 pandemic. We found most responses were worried about they might not receive good health care when they join a clinical trial (p=0.04). Moreover, most of them were afraid about they might the are not able to find transportation to reach them to the clinical trial treatment center (p=0.03).

While most of them were willing to participate if they received benefits, risks, and full information about the trials (p=0.004). Also, most of them were willing to participate in a clinical trial if their physician explained it to them (p=0.003). The majority of them preferred to have more information from their physician about the trial (p=0.007).

Discussion

In this cross-sectional study, we found that the COVID-19 pandemic has had no impact on patient knowledge about clinical trials but has slightly affected patient attitudes about participating in clinical trials. Only 8% of the participants had previously participated in clinical trials. Generally, people had some basic knowledge about randomized, controlled trials, including awareness about the need for approval by the government. However, patients knew less about the requirements for reporting adverse events and the concept of informed consent. Knowledge

Table 3 Attitudinal of Fear from Participating in a Clinical Trial

Survey Item		Total		Before COVID19 Pandemic		During COVID19 Pandemic		P-value	
		n	%	n	%	n	%	1	
I am afraid of the side effects that I will have on a clinical trial.	Strongly agree Agree Neutral Disagree	178 315 193 84	21.7 38.3 23.5 10.2	71 155 83 36	8.6 18.9 10.1 4.4	107 160 110 48	13.01 19.5 13.4 5.8	0.3	
	Strongly disagree	52	6.3	24	2.9	28	3.4		
I am worried that the treatment I'd receive on a clinical trial would not work for me.	Strongly agree. Agree Neutral Disagree Strongly disagree	96 273 258 133 62	11.7 33.2 31.4 16.2 7.5	48 121 106 62 32	5.8 14.7 12.9 7.5 3.9	48 152 152 71 30	5.8 18.5 18.5 8.6 3.6	0.4	
I would not ask about clinical trials unless my doctor brought them up first.	Strongly agree. Agree Neutral Disagree Strongly disagree	113 365 145 134 65	13.8 44.4 17.6 16.3 7.9	54 179 57 50 29	6.6 21.8 6.9 6.1 3.5	59 186 88 84 36	7.2 22.6 10.7 10.2 4.4	0.1	
I do not like to try new treatments until they have been approved to be used.	Strongly agree. Agree Neutral Disagree Strongly disagree	279 336 132 50 25	33.9 40.9 16.1 6.1 3.04	128 158 53 20 10	15.6 19.2 6.5 2.4 1.2	151 178 79 30 15	18.4 21.7 9.6 3.6 1.8	0.6	
l do not trust drug companies.	Strongly agree. Agree Neutral Disagree Strongly disagree	83 160 306 207 66	10.1 19.5 37.2 25.2 8.02	38 76 145 79 31	4.6 9.2 17.6 9.6 3.8	45 84 161 128 35	5.5 10.2 19.6 15.6 4.3	0.3	
I am afraid I will be used as a test subject if I join in a clinical trial.	Strongly agree. Agree Neutral Disagree Strongly disagree	122 296 190 153 61	14.8 36.01 23.1 18.6 7.4	61 137 75 65 31	7.4 16.7 9.1 7.9 3.8	61 159 115 88 30	7.4 19.3 14 10.7 3.7	0.3	
I am worried that going on a clinical trial would burden my family.	Strongly agree. Agree Neutral Disagree Strongly disagree	139 290 176 166 51	16.9 35.3 21.4 20.2 6.2	60 122 89 72 26	7.3 14.8 10.8 8.8 3.2	79 168 87 94 25	9.6 20.4 10.6 11.4 3.04	0.4	
I am worried that my family would not allow me to participate in a clinical trial.	Strongly agree. Agree Neutral Disagree Strongly disagree	143 275 167 168 69	17.4 33.5 20.3 20.4 8.4	58 123 66 88 34	7.1 15 8.03 10.7 4.1	85 152 101 80 35	10.3 18.5 12.3 9.7 4.3	0.1	

(Continued)

Survey Item	vey Item		1	Before COVID19 Pandemic		During COVID19 Pandemic		P-value
		n	%	n	%	n	%	
I am worried that my medical care will not be as good if I join a clinical trial.	Strongly agree. Agree Neutral Disagree Strongly disagree	89 237 192 213 91	10.8 28.8 23.4 25.9 11.1	34 112 81 110 32	4.1 13.6 9.9 13.4 3.9	55 125 111 103 59	6.7 15.2 13.5 12.5 7.2	0.04
I would not be able to find transportation to get me to my clinical trial treatment center.	Strongly agree. Agree Neutral Disagree Strongly disagree	67 253 268 175 59	8.2 30.8 32.6 21.3 7.2	28 128 104 87 22	3.41 15.6 12.6 10.6 2.7	39 125 164 88 37	4.7 15.2 20 10.7 4.5	0.03
I would not be able to keep up with the clinical trial treatment schedule.	Strongly agree. Agree Neutral Disagree Strongly disagree	71 281 225 197 48	8.6 34.2 27.4 24 5.8	32 138 96 82 21	3.9 16.8 11.7 10 2.6	39 143 129 115 27	4.7 17.4 15.7 14 3.3	0.5
I do not trust the medical system.	Strongly agree. Agree Neutral Disagree Strongly disagree	31 73 222 285 211	3.8 8.9 27.01 34.7 25.7	13 33 93 139 91	1.6 4.01 11.3 16.9 11.1	18 40 129 146 120	2.2 4.9 15.7 17.8 14.6	0.6
I do not have time to take part in a clinical trial.	Strongly agree. Agree Neutral Disagree Strongly disagree	166 282 211 114 49	20.2 34.3 25.7 13.9 6	74 124 92 57 22	9 15.1 11.2 6.9 2.7	92 158 119 57 27	11.2 19.2 14.5 6.9 3.3	0.8
Helping in developing new medications	Strongly agree. Agree Neutral Disagree Strongly disagree	144 406 153 78 41	17.5 49.4 18.6 9.5 5	62 196 55 39 17	7.5 23.8 6.7 4.7 2.1	82 210 98 39 24	10 25.5 11.9 4.7 3	0.1
Being part of scientific knowledge	Strongly agree. Agree Neutral Disagree Strongly disagree	121 387 182 88 44	14.7 47.1 22.1 10.7 5.4	55 184 74 37 19	6.7 22.4 9 4.5 2.3	66 203 108 51 25	8.03 24.7 13.1 6.2 3.04	0.6
Willing to participate if you were provided with a good consent form explaining the clinical trial's benefits and risks.	Strongly agree. Agree Neutral Disagree	88 334 199 129	10.7 40.6 24.2 15.7	53 160 77 49	6.5 19.5 9.4 6	35 174 122 80	4.3 21.2 14.8 9.7	0.004

Strongly disagree

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8.8

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(Continued)

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3.7

42

5.I

Table 3 (Continued).

Survey Item		Total		Before COVID19 Pandemic		During COVID19 Pandemic		P-value
		n	%	n	%	n	%	
Willing to participate in a clinical trial if you were explained in a completely private setting	Strongly agree. Agree Neutral Disagree Strongly disagree	68 288 207 175 84	8.3 35.04 25.2 21.3 10.2	38 140 86 71 34	4.6 17.03 10.5 8.6 4.14	30 148 121 104 50	3.7 18 14.7 12.7 6.08	0.1
Willing to participate in a clinical trial if your physician explained you	Strongly agree. Agree Neutral Disagree Strongly disagree	65 295 209 167 86	7.9 35.9 25.4 20.3 10.5	39 148 88 63 31	4.7 18 10.7 7.7 3.7	26 47 2 04 55	3.2 17.9 14.7 12.7 6.7	0.003
Having religious representatives in the clinical trial and an ethics committee will make you more likely to participate in the clinical trial.	Strongly agree. Agree Neutral Disagree Strongly disagree	70 216 258 186 92	8.5 26.3 31.4 22.6 11.2	31 100 114 85 39	3.8 12.2 13.9 10.3 4.7	39 116 144 101 53	4.7 14.1 17.5 12.3 6.5	0.9
A belief that by participating in a clinical trial, you will receive the best medical care	Strongly agree. Agree Neutral Disagree Strongly disagree	71 312 266 125 48	8.6 38 32.4 15.2 5.8	34 152 112 50 21	4.14 18.5 13.6 6.1 2.6	37 160 154 75 27	4.5 19.5 18.7 9.1 3.3	0.4
Willing to participate in a clinical trial if you were with a family member when a researcher explains clinical trial.	Strongly agree. Agree Neutral Disagree Strongly disagree	33 239 250 220 80	4.01 29.1 30.4 26.8 9.7	17 114 114 93 31	2.1 13.9 13.9 11.3 3.8	16 125 136 127 49	2 15.2 16.5 15.5 6	0.5
Willing to participate in a clinical trial if you had more time to think about it.	Strongly agree. Agree Neutral Disagree Strongly disagree	54 299 185 195 89	6.6 36.4 22.5 23.7 10.8	33 148 73 81 34	4.01 18 8.9 9.9 4.14	21 151 112 114 55	2.6 18.4 13.6 13.9 6.7	0.01
Willing to participate in a clinical trial if you could obtain information from your physician	Strongly agree. Agree Neutral Disagree Strongly disagree	58 338 187 155 84	7.1 41.1 22.7 18.9 10.2	37 159 82 61 30	4.5 19.3 9.9 7.4 3.6	21 179 105 94 54	2.6 21.8 12.8 11.4 6.6	0.007
l completely trust my doctor's recommendations about a clinical trial	Strongly agree. Agree Neutral Disagree Strongly disagree	69 346 247 123 37	8.4 42.1 30.1 15 4.5	33 162 108 55 11	4.01 19.7 13.1 6.7 1.3	36 184 139 68 26	4.4 22.4 17 8.3 3.2	0.4

(Continued)

Table 3 (Continued).

Survey Item		Total		Before COVID19 Pandemic		During COVID19 Pandemic		P-value
		n	%	n	%	n	%	
I am worried about the safety of participating in a clinical trial	Strongly agree. Agree Neutral Disagree Strongly disagree	3 336 236 84 35	15.9 40.9 28.7 10.2 4.3	64 169 94 31 11	7.8 20.6 11.4 3.8 1.3	67 167 142 53 24	8.2 20.3 17.3 6.5 2.9	0.02
I trust the information I read about a clinical trial on the internet	Strongly agree. Agree Neutral Disagree Strongly disagree	28 138 299 253 104	3.4 16.8 36.4 30.8 12.7	9 59 125 124 52	1.1 7.16 15.2 15.1 6.3	19 79 174 129 52	2.3 9.6 21.2 15.7 6.3	0.2
Clinical trial medications are safer than other medication	Strongly agree. Agree Neutral Disagree Strongly disagree	23 96 312 256 135	2.8 11.7 37.9 31.1 16.4	7 39 152 114 57	0.9 4.7 18.5 13.9 6.9	16 57 160 142 78	2 6.9 19.5 17.3 9.5	0.3

about the process of informed consent and about the role of the ethics committee increased during the pandemic.

Only a few studies in Saudi Arabia have been conducted to assess factors that affect participation in clinical trials.^{5,6} A study conducted by Al-Tannir et al found that 80% of the participants considered clinical trials essential for improving patient care and scientific knowledge.⁵ Regarding informed consent in that study, most participants reported awareness of confidentiality, expected risks, and benefits; however, knowledge about possible compensation, rights, and consequences of withdrawal was lower.⁵

Another study by Al-Rawashdeh et al found that the vast majority of participants were unaware of the institutional review board.⁶ Evidence from these studies cannot be extrapolated to the setting of our study. During the COVID-19 pandemic, the number of clinical trials has greatly increased.⁹ Therefore, public knowledge and attitudes toward enrollment in clinical trials are expected to increase simultaneously. In this study, participants were more receptive to the benefits of clinical trials during COVID-19. In addition, study participants demonstrated higher levels of trust in the health care system compared with previously reported levels. Abu-Farha et al assessed the public perception of clinical trials during COVID-19;¹⁰ 68% and 73% of the Jordanian public were willing to participate in COVID-19 clinical trials to find treatment and return to normal life respectively. This high percentage reflects the increased societal responsibility of the general public toward COVID-19 trials.

This study was one of the few studies, to our knowledge, that assessed the general public's perception and knowledge of clinical trials during COVID-19.10 This study had some limitations. First, this study was conducted in two medical cities in Riyadh. Second, the vast majority of participants were relatively young and educated. Therefore, results cannot be generalizable to different age groups, educational levels, or settings. Moreover, the survey was self-administered, therefore the risk of social desirability bias might be introduced.¹¹ Finally, the research questionnaire was developed by the research team. Future studies should aim to develop a standardized tools which enable researcher to quantify the public attitude to clinical trials which in turn help in assessing the impact of policies and intervention that affect patients recruitment.

Social media has a major role in educating the public about clinical trials and COVID-19.^{12,13}

Simple, jargon-free language can explain the various aspects of clinical trials, including the potential benefits and risks. In addition, encouraging clinical trial participants to share their experiences could help recruit future eligible participants. These interactions should be regulated by entities that manage patient and public involvement in clinical trials. The involvement of patients and the public in improving awareness about clinical trials represents a substantial role in bridging the gap between researchers and the public.¹⁴ Efforts to reach patients can involve reviewing study documents to assess their appropriateness and clarity for the study participants, evaluating patient experiences, and disseminating study results to the public. In addition, the National Committee of Bioethics, the Ministry of Health, or research centers must conduct several awareness campaigns about the role of ethics committees and introduce patients who were enrolled in clinical trials before the community to transfer their experience about clinical trials.

Conclusion

The COVID-19 pandemic has had no impact on patient knowledge about clinical trials; however, the pandemic did have a slight impact on patient attitudes toward participating in clinical trials. The Saudi population knows about clinical trials but lacks knowledge about the role of the ethics committee and about informed consent. Also, most people do not have the experience of participating in a clinical trial. Still, they maintain moderately positive attitudes toward clinical trials. The conclusion needs to be interpreted with caution due to small sample and the high representation of young, educated subjects in comparison with other population groups.

Disclosure

The authors report no conflicts of interest for this work.

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