

BARRIERS AND WILLINGNESS AMONG PHYSICIANS TOWARD PARTICIPATION IN CLINICAL TRIALS

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ABSTRACT

Background: Several barriers face physicians with their participation in clinical trials. **Aim of Study:** To identify barriers to physicians' participation in clinical trials. **Methods:** An analytical cross-sectional design was followed during October-December 2019. The study included 142 clinicians in Al-Hada Military Hospital, Taif City, Saudi Arabia. A self-administered questionnaire was constructed for data collection. It consisted of personal characteristics and 24 statements about possible barriers against participation in clinical trials. **Results:** Most participants (71.8%) were willing to participate in clinical trials, while 57.7% never participated in any clinical trials. Previous participation in clinical trials was significantly higher among non-Saudi than Saudi physicians (62.5% and 34.3%, respectively, $p=0.002$); it was more among consultants and specialists than residents (65.7%, 48.3%, and 29.5%, respectively, $p=0.001$); and it was significantly higher among physicians with more experience in clinical practice ($p<0.001$). Multivariate binary logistic regression model revealed that physicians' age group, position, and willingness to participate in clinical trials were significantly associated with their previous participation in clinical trials ($p=0.013$, $p=0.011$, and $p=0.010$, respectively). The main barriers against physicians' participation in clinical trials were the absence of motivation or encouragement to participate in clinical trials (78.9%), lack of training in clinical trials (77.5%), the long time required to conduct clinical trials (70.4%), and the lack of free time (69%). **Conclusions:** The majority of clinicians in Al-Hada Military Hospital, Taif City, Saudi Arabia were willing to participate in clinical trials. However, most of them, especially Saudi and those with less experience in clinical practice, did not participate in clinical trials. There were several barriers against physicians' participation in clinical trials, such as the absence of motivation or encouragement to participate, lack of training, the long time required to conduct clinical trials, and the lack of free time.

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Introduction

Clinical trials are studies that examine how new medical approaches are applied to people [1-3] and what are their effects [4]. Each study attempts to find answers to scientific questions and better methods to prevent, screen for, diagnose, or treat different diseases [5]. Clinical research has the potential to provide the best evidence to treatments and diagnostic approaches [6]. Clinical trials, predominantly those on human subjects including patients and other volunteers, are essential to recognize or verify the influences of interventions and identify any adverse impacts to investigational products in different populations [7, 8].

It is to be noted that, there are excessive differences in cultures and perceptions across the globe, and what is appropriate in one area might not be in another [9]. For instance, some interventions that were revealed to be effective in high-income countries were not similarly operational when utilized in other settings [10, 11].

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Ross et al. conducted a systematic review to investigate barriers against physicians' engagement and participation in clinical trials for cancer and other illnesses, they reported that the major barrier was lack of time [12]. Another systematic review recognized other barriers, such as system organization barriers, e.g., time involvement and resource concerns, trial design-related barriers, and physician-related barriers [13]. Lang et al. reported that, although many of the issues confronting clinical trials working in resource-limited settings are comparable, the human and other resource capacities of developing countries lag far behind that accessible in wealthier nations [14].

Many authors who operated as clinical investigators in different countries have published their perspectives regarding the problems of participating in clinical trials. Administrative concerns, absence of infrastructure, ethical and regulatory issues, absence of finance, poor data quality, and absence of training focusing on clinical research were the main barriers [15-17].

Compared to developed countries, clinical trials are not common in Saudi Arabia [18]. Therefore, there is a pressing need to conduct studies that identify different barriers regarding the participation of physicians in Saudi Arabia in clinical trials [19, 20].

This study aimed to identify barriers to physicians' participation in clinical trials in Al-Hada Military Hospital, Taif City, Saudi Arabia.

Methodology

Following an analytical cross-sectional design during the period from October 2019 till December 2019, the present study was conducted at Al-Hada Military Hospital, Taif City, Saudi Arabia. All clinicians of various specialties with at least one year of clinical experience at the study hospital were invited (N=160). Newly appointed (i.e., less than one year) clinicians were excluded.

Based on a thorough review of relevant literature, a self-administered questionnaire was constructed by the researchers in a simple English language. The study questionnaire contained two parts. The first part included participants' personal characteristics, i.e., sex, age, nationality, position, specialty, years of clinical experience, and participants' current willingness and previous participation in clinical trials. The second part included 24 statements about likely barriers against participation in clinical trials. Participants were asked to respond by: Agree, Uncertain, or Disagree.

The contents of the study questionnaire were validated by two community medicine consultants and one expert in clinical research. The internal consistency was assessed from the data of the first phase of the pilot study by applying Cronbach's alpha coefficient (Cronbach's alpha=0.81). A pilot research was conducted on 18 clinicians in a Prince Mansour Military hospital. The pilot investigation aimed to examine the clarity and wording of the data collection tool. Within the pilot research, the questionnaire was applied twice, one week apart, to evaluate its "test-retest" reliability of the total score (test-retest, $r=0.805$).

The Ethical Approval for conducting this study was obtained from the Research & Ethics Committee, Western Region, Medical Services General Directorate (#2019-415). A total of 142 clinicians participated in the current investigation (response rate = 88.8%). The anonymity of participants and confidentiality were fully guaranteed throughout the research. Collected data were kept secured and were used only for research purposes.

Data were collected, tabulated, and statistically evaluated by means of the Statistical Package for Social Sciences (IBM, SPSS, Version 25). Data were expressed as frequency and percentages. Chi-Square test (χ^2) was applied to evaluate the significance of differences in frequencies. Multivariate binary logistic regression was applied to control for possible confounders. P-values less than 0.05 were considered as statistically significant.

Results

Table (1) shows that 73.2% of the participants were males. The age of 43% of participants was less than 30 years, while that of 33.8% of participants was 30-40 years and that of 23.2% was more than 40 years. Most participants (71.8%) were Saudi. The specialty of 34.5% of participants was medicine, 23.2% were surgeons, 13.4% were obstetricians/gynecologists, 18.3% were pediatricians, and 10.6% had other specialties (Figure 1). More than half of participants (54.9%) were residents, while 20.4% were specialists and 24.6% were consultants. The years of clinical experience of most participants (71.1%) were ≤ 10 years, while 28.9% had more than 10 years of experience. Figure (1) shows that 71.8% of participants were willing to participate in clinical trials, while 28.2% were not willing. Figure (2) shows that 42.3% of participants had previous participation in clinical trials, while 57.7% had never participated in any clinical trials.

Table 1: Personal characteristics of the participants.

Personal Characteristics	Frequency	Percentage
Gender		
Male	104	73.2
Female	38	26.8
Age groups		
<30 years	61	43.0
30-40 years	48	33.8
>40 years	33	23.2
Nationality		
Saudi	102	71.8
Non-Saudi	40	28.2
Specialty		
Medicine	49	34.5
Surgery	33	23.2
Obstetrics and Gynecology	19	13.4
Pediatrics	26	18.3
Others	15	10.6
Position		
Resident	78	54.9
Specialist	29	20.4
Consultant	35	24.6
Years of clinical experience		
≤10 years	101	71.1
>10 years	41	28.9

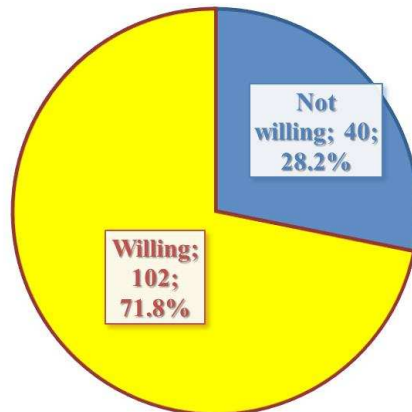


Figure 1: Physicians' willingness to participate in clinical trials.

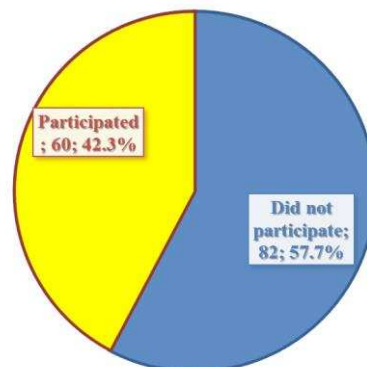


Figure 2: Physicians' previous participation in clinical trials.

Table (2) displays that previous participation in clinical trials was significantly higher among non-Saudi than Saudi physicians (62.5% and 34.3%, respectively, $p=0.002$). Previous participation in clinical trials was significantly higher among consultants and specialists than residents (65.7%, 48.3%, and 29.5%, respectively, $p=0.001$). Previous participation in clinical trials was significantly higher among participants with more experience in clinical practice ($p<0.001$). Nevertheless, participants' participation in clinical trials did not vary significantly based on their gender, age group, or specialty.

Table 2: Participants' previous participation in clinical trials according to their personal characteristics.

Personal characteristics	Did not participate (n=82)		Participated(n=60)		P-value
	No.	%	No.	%	
Gender					
Male	63	60.6	41	39.4	0.259
Female	19	50.0	19	50.0	
Age groups					
<30 years	40	65.6	21	34.4	0.095
30-40 years	28	58.3	20	41.7	
>40 years	14	42.4	19	57.6	
Nationality					
Saudi	67	65.7	35	34.3	0.002
Non-Saudi	15	37.5	25	62.5	
Specialty					
Medicine	26	53.1	23	46.9	0.347
Surgery	23	69.7	10	30.3	
Pediatrics	16	61.5	10	38.5	
Ob/Gyn	11	57.9	8	42.1	
Others	6	40.0	9	60.0	
Position					
Resident	55	70.5	23	29.5	0.001
Specialist	15	51.7	14	48.3	
Consultant	12	34.3	23	65.7	
Experience in clinical practice					
≤10 years	68	67.3	33	32.7	<0.001
>10 years	14	34.1	27	65.9	

Table (3) shows that the multivariate binary logistic regression model revealed that physicians' age group, position, and willingness to participate in clinical trials were significantly associated with their previous participation in clinical trials ($p=0.013$, $p=0.011$ and $p=0.010$, respectively). Table (4) shows that the main barriers against physicians' participation in clinical trials were absence of motivation or encouragement to participate in clinical trials (78.9%), absence of training in clinical trials (77.5%), the long time required to conduct clinical trials (70.4%), and the lack of free time (69%)

Table 3: Binary logistic regression model for participants' previous participation in clinical trials.

Independent Variables	B	SE	Wald	Exp(B)	P-value	95% CI for Exp(B)	
						Lower	Upper
Gender	0.590	0.435	1.840	1.804	0.175	0.769	4.230
Age Groups	-1.385	0.555	6.222	0.250	0.013	0.084	0.743
Position	1.271	0.497	6.546	3.563	0.011	1.346	9.432
Experience	1.003	0.750	1.788	2.728	0.181	0.627	11.870
Specialty	0.188	0.149	1.599	1.207	0.206	0.902	1.617
Nationality	0.657	0.620	1.125	1.930	0.289	0.573	6.503
Willingness to participate in clinical trials	1.259	0.490	6.612	3.523	0.010	1.349	9.201
Constant	-4.323	1.061	16.611	0.013	0.000		

Table 4: Barriers against physicians' participation in clinical trials.

Barrier	Disagree		Uncertain		Agree	
	No.	%	No.	%	No.	%
Clinical trials did not alter practice in meaningful ways	102	71.8	29	20.4	11	7.7
Clinical trials are not needed	98	69.0	24	16.9	20	14.1
There is insufficient training in clinical trials	15	10.6	17	12.0	110	77.5
There is no motivation or encouragement to participate in a clinical trial	18	12.7	12	8.5	112	78.9
There is insufficient number of patients for clinical trial	77	54.2	25	17.6	40	28.2
It is difficult to recruit patients in clinical trials	22	15.5	23	16.2	97	68.3
It is better to do clinical practice than to participate in a clinical trial	30	21.1	28	19.7	84	59.2
There is no support for clinical trials by other physicians in the hospital	26	18.3	33	23.2	83	58.5
There is no support for clinical trials by hospital administration	45	31.7	41	28.9	56	39.4
There are no researchers at the hospital	30	21.1	33	23.2	79	55.6
There is no support by research personnel at the hospital to participate in clinical trials	21	14.8	37	26.1	84	59.2
Opportunities are limited to collaborate with researchers in other centers	15	10.6	37	26.1	90	63.4
There is high competition among researchers studying similar topics	69	48.6	42	29.6	31	21.8
There are no expert biostatisticians	14	9.9	35	24.6	93	65.5
It is difficult to obtain ethical approval	16	11.3	51	35.9	75	52.8
It is difficult to obtain consent from patients	26	18.3	33	23.2	83	58.5
Consent forms of clinical trials are lengthy and complex	18	12.7	36	25.4	88	62.0
There are concerns about risk or harm	19	13.4	40	28.2	83	58.5
Patients prefer that physicians decide about group enrollment rather than randomization	36	25.4	56	39.4	50	35.2
Large time is required to conduct clinical trials	12	8.5	30	21.1	100	70.4
Clinicians do not have much free time	13	9.2	31	21.8	98	69.0
There is no funding for clinical trials in my specialty	9	6.3	54	38.0	79	55.6
There is no funding for clinical trials in prevention	8	5.6	56	39.4	78	54.9
There is no funding for large clinical trials	10	7.0	50	35.2	82	57.7

Discussion

Physicians can act as 'double agents' to improve the quality of provided healthcare services and clinical research. Nevertheless, although clinical research is the key to the advancement of medical knowledge, most physicians face several barriers concerning participation in clinical research in general and clinical trials in particular [21]. Consequently, the current investigation aimed to explore barriers against physicians' participation in clinical trials. This study revealed that most participants expressed a positive attitude toward adopting and executing clinical trials. Almost three-fourths of physicians (71.8%) were willing to participate in clinical trials, while less than half of physicians (42.3%) had previous participation in clinical trials. This study also revealed that participation in clinical trials was significantly more among non-Saudi than non-Saudi physicians, significantly more among consultants and specialists than residents, and also significantly more among those with higher experience in clinical practice. Multivariate binary logistic regression model revealed that physicians' age group, position, and willingness to participate in clinical trials were significantly associated with their previous participation in clinical trials. These findings are in accordance with those of Al-Tannir et al. [15], who reported that 61.7% of physicians at King Fahad Medical City, Riyadh, Saudi Arabia, stated their willingness to facilitate and assist in clinical trials, while 35.9% previously participated in clinical trials. In Boston, Massachusetts, USA, Getz reported that only 14.3% of physicians in the Center for the Study of Drug Development, Tufts University School of Medicine, participated as investigators, clinical research coordinators, or as subjects in clinical trials [22]. The high willingness of physicians to facilitate or participate in clinical trials can be attributed to the sufficient knowledge about their important role as investigators, and the expected benefits for participation [23]. The significantly more frequent participation in clinical trials observed among non-Saudi than Saudi physicians as well as senior physicians can be attributed to the high-standard international selection criteria for non-Saudi physicians' employment, and possibly suboptimal teaching of research within the undergraduate curricula at the Saudi colleges of medicine. Chen et al. suggested that physicians should receive education and training on research design. Research should be practiced within their undergraduate medical curricula and to be reinforced through continuing medical education after graduation [24].

Findings of the present study revealed that the main barriers against physicians' participation in clinical trials were the absence of motivation or encouragement to participate in clinical trials, lack of being trained on clinical trials, the large time

needed to conduct clinical trials and the time constraint to conduct or participate in clinical trials. The barriers that were significantly associated with physicians' willingness to participate in clinical trials were difficulty to recruit patients, the preference to do clinical practice than to participate in a clinical trial, absence of support for clinical trials, absence of researchers at the hospital, absence of support to participate in clinical trials, the high competition among researchers studying comparable topics, absence of expert biostatisticians, difficulty to get ethical approval, the long time needed to conduct clinical trials, and shortage of free time. Alemayehu *et al.* stressed that barriers against physicians' participation in clinical trials happen at all levels, i.e., system, institute, and clinicians. The most common barriers facing clinical researchers are the lack of financial and human capacity, ethical obstacles, improper research environment, and operational barriers [16]. Hudson *et al.* reported that time constraint was a great barrier affecting trial participation, especially due to the extra paperwork associated with clinical trials [25]. Tournoux *et al.* also showed trial follow-up time and time spent discussing trials with patients signify noteworthy clinician-related barriers to trial involvement [26]. Mahmud *et al.* added that recruitment and extended follow-up of patients for clinical trial and explanation of the trial to them (i.e., patient education) are challenging barriers. They suggested that streamlining the paperwork in clinical trials could reduce time commitment [27]. Harris noted that, in developing countries, research is a luxury, mainly due to economic constraints. Allocating funds for research is limited [28]. Ethical and regulatory issues, administrative matters, lack of finance, absence of infrastructure, poor data quality, and lack of training curricula focusing on clinical research were the major barriers facing physicians [17, 18, 29, 30]. Nundy and Gulhati stated that in developing countries, colleges of medicine and teaching hospitals inadequately prepare their graduates to engage in research or clinical trials [31]. Moreover, physicians are already overloaded with patient care and do not have free time for participating in clinical trials [32]. Therefore, learning from and adapting best practices at all levels (system, organizational and individual) could be beneficial to deal with and overcome barriers in conducting clinical trials. It is necessary to establish a national-level support group that offers guidance support for the whole clinical trial process, (from funding attainment to final report writing), and to perform an advocacy role in funding and numerous regulatory processes [33].

Conclusions

Most clinicians in Al-Hada Military Hospital, Taif City, Saudi Arabia are willing to participate in clinical trials. However, more than half of them have never participated in any clinical trials. Participation in clinical trials is significantly higher among non-Saudi than Saudi clinicians; more among consultants and specialists than residents; and is significantly higher among those with more experience in clinical practice. The leading barriers against physicians' participation in clinical trials are lack of motivation or encouragement to participate in clinical trials, lack of training in clinical trials, the large time required to conduct clinical trials, and lack of free time. Therefore, all physicians should receive more education and training in research design. Research should be practiced within their undergraduate medical curricula and to be reinforced through continuing medical education after graduation.

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