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Original Research Article

Awareness and attitude of Saudi cancer patients toward participation in clinical research

Nagham Sheblaq[1]*, Marwan ElBagoury[2], Ahmed M. Elagouz[3], Maryam Kotb[3]

[1]Department of Oncology, King Abdul Aziz Medical City for National Guard, Riyadh, Saudi Arabia
[2]Ulm University – Faculty of Medicine, Ulm, Germany
[3]University of The People, Pasadena, California

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***Correspondence:**
Dr. Nagham Sheblaq,
E-mail: naghamramzi1@gmail.com

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ABSTRACT

Background: Public awareness about the importance of clinical research (CR) is crucial for patient's participation in clinical trials. Their enrollment may be impacted by their levels of awareness and attitudes toward participation. Our study aimed to assess the Saudi cancer patient's knowledge and perception about CR, and determine the influencing factors and barriers affecting participation.
Methods: A cross-sectional study was conducted in 300 cancer patients attending the Oncology Department at King AbdulAziz Medical City (KAMC) Riyadh between February 2011 and February 2012 using a survey covering the demographic data, knowledge of clinical research, and attitude toward participation; followed by statistical analysis.
Results: A total of 300 patients were enrolled in the study with a median age of 53.6 (42.2-64.01); 62.67% of which were females. The majority of patients (97.31%) were not aware of Institutional Review Board (IRB). However, (75.33%) showed interest in CR participation, if offered. The advanced disease (86.67%), and the lack of other treatment options (85.33%) were the top two encouraging factors, while fear of adverse side effects (58.33%), and the unknown efficacy of treatment (58.32%) were the top two barriers against participation. Respondents younger than 45 years, and educated ones were significantly more interested in participation in CR with P values P=0.0136 and P=0.0239 respectively.
Conclusions: There is an apparent gap in cancer patient's awareness about CR. However, there is an obvious interest in participation in CR especially in younger and educated patients. Enhancing public awareness is crucial to improve participation in CR.

Keywords: Awareness, Cancer, Clinical research, Saudi

INTRODUCTION

Clinical trials are essential for the identification of effective therapies in modern medicine. As researchers achieve a greater understanding of diseases, a growing number of new opportunities will require increasing numbers of patients agreeing to participate in clinical trials.[1] Public awareness about the need for clinical research and the benefits beyond participation is important. Although the main objective of clinical trials is to provide a high standard of care and help in advancement of medical knowledge, only a small portion of patients receive treatment as a part of a formal clinical trial.[2]

Among the significant barriers to participation in clinical research are the frequent misconceptions about clinical trials; which arise primarily due to lack of adequate information from the treating physician, complexity of the study procedure, preferences of patients regarding a

particular treatment or no treatment, uncertainty and the experimental nature of a clinical trial (additional side effects, less known about the treatment), and concern about confidential information.[2-5] Perceptions of health individuals differ from those of patients since patients may be stressed and feel helpless after being diagnosed of their illness; which has a negative impact on patient's attitude towards a trial.[3-6]

Low levels of participation are also influenced by factors affecting both physician and patient, the perception of the family members, lack of trust in the medical system, and in some cases, the level of disease severity or seriousness (such as cancer end stages) play a major role in their willingness.[4]

Studies of physician and patient communication revealed that patients who felt that their physicians had communicated clearly about clinical trial were more likely to participate and build a trust-based relationship throughout their enrolment period. Moreover, physicians have to think of appropriate recruitment approaches in order to help patients make better decisions regarding participation in clinical trials.[7,8] Understanding all the mentioned factors will help clinical research professionals improve patient's perceptions of participation in clinical trials, and thus increase the enrolment rates.[7]

Although patients trust their treating physicians, some studies showed that the active involvement of some key personnel such as clinical research coordinators, nurses and clinical research assistants also had a great influence as they were more informed about the available protocols than physicians. Therefore, strategies must be developed to involve such professionals in helping patients with their decisions.[9-11] Furthermore, nurses play an important role in relieving the participation decision related stress.[12]

Some recommendations can be developed to public regarding awareness of and attitudes toward clinical trials. For physicians, it is recommended that the trial should address an important medical question, be conducted by an adequate and well trained staff, and be as clear and simple as possible. For patients, it is important to understand purposes of the clinical trial and maintain a good relationship with research team members.[13-15]

The ability to recruit patients for future clinical trials will depend, in particular, on understanding the barriers against participation in clinical trials. Unfortunately, there is no enough data about cancer patient's awareness of and attitudes toward participation in clinical trials in Kingdom of Saudi Arabia. Only three studies have investigated Saudi patient's awareness of and attitudes toward CR. The first one investigated the awareness and perceptions of clinical trials in cancer patients and their families in Saudi Arabia, and was published in 2015, the second one assessed the knowledge, attitudes, and perceptions of Saudis towards participating in clinical trials (CTs), and was published in 2016, and the last one determined barriers that prevent Saudi cancer patients from participating in a CTs, and was published in 2017.[16-18] Therefore, the current study was conducted to help address this issue, cover this literature gap, provide data about the awareness levels and attitudes of the cancer patients under study toward CR, and improve the accrual rate into future CTs.

METHODS

Study design

A cross-sectional survey was conducted at KAMC for National Guard-Riyadh, Kingdom of Saudi Arabia between February 2011 until February 2012, using a close ended questionnaire that aimed to identify the knowledge of Saudi adult cancer patients about clinical research process, assess their willingness to participate in clinical research, and determine the influencing factors toward participation in clinical research, and the barriers against it as well.

An Institutional Review Board approval was obtained and registered at clinical trial.gov database (NCT 02042469). All consecutive patients attending the oncology department with cancer diagnosis, 18 years and above were eligible to participate in the survey, where patients who refused to complete the survey were excluded.

Patients were approached by trained clinical research coordinators using an interview based questionnaire composed of close ended questions. The purpose of the survey was explained, and verbal informed consent was obtained from each patient. The questionnaire was translated into Arabic and modified from the one used in previous studies to comply with our patient's culture.[1, 3, 5]

A pilot survey was conducted and assessed in the first ten patients, and then modified accordingly.

Demographic data, knowledge of clinical research, and attitude toward participation in clinical research were covered by the questionnaire as follows:

- *Demographic data:* including age, sex, marital status, occupation, and education level.
- *Knowledge of clinical research:* three questions were dedicated to addressing their knowledge; if they know about an IRB? If they have been asked to participate in any clinical research? and who approached them (physician, nurse, research coordinator or others)?
- *Attitude toward participation in CR:* questions were based on a 30 items scale developed from focus group data and review of literature. Questions measured the impact of individual items on patient's willingness and refusal toward participation in CTs. Respondents indicated their level of agreement or disagreement on a 5-points Likert scale (1=strongly

agree, 2=agree, 3=neither agree nor disagree, 4=disagree, 5=strongly disagree).

Moreover, general questions were included regarding respondent's awareness of available clinical trials at oncology department, how they would like to see future announcements, and complexity of the survey.

Analysis

All surveys were checked for completion by Clinical Research Coordinators, entered into a customized excel database, and then data entries were validated. Data from the pilot study were used to refine the survey. Items of responses were examined for completeness and internal consistency. Acceptability and comprehension of the survey were examined by asking the patients a few questions. Data of all enrolled patients were used for analysis.

Descriptive statistics were applied for the whole study sample. Counts and percentages (%) were used to summarize a categorical variable of demographic and clinical characteristics, median (range) was used for continuous variables, while exploratory analysis was conducted by age group and gender.

The sample size calculation was conducted assuming that the primary measure of the study would be represented in proportions.

In order to determine the number of respondents required to be interviewed to achieve results that reflect the target population with 5% level of precision, the confidence interval was calculated using Wilson score interval method for binomial proportion.

Assuming that a conservative proportion of 50% of the respondents would answer a question in a specific manner, a sample size of 300 was sufficient to ensure that the desired precision (a 2-sided 95% confidence interval width of 10% (half width of 5%) is achieved with 99% probability. This sample size was obtained using the one sample frequency procedure in PROC POWER (SAS Version 9.2).

Associations between potential determinants and respondent's answers were estimated using odds ratios (OR) and the corresponding 95% confidence intervals (CI). All analyses were conducted and reported using SAS V9.1, SAS institution, NC-USA, and a 2-tailed p value ≤0.05 was accepted as significant.

RESULTS

Demographic data

Three hundred cancer patients attending the Oncology Department at KAMC Riyadh were enrolled in the study.

Table 1 showed demographics data. Males and females represented 112 (37.33%) and 188 (62.67%) respectively. Ages ranged from 42.22 to 64.01 with a median of 53.62 years. The majority 297 (99.00%) were Saudi, while only 3 (1.00%) were non-Saudi. Educated and non-educated patients represented 194 (64.67%) and 106 (35.33%) respectively. The majority of 256 (85.33%) were unemployed.

Table 1: Demographic data of respondents.

Variable	Count	Percentage (%)
Gender		
Female	188	62.67
Male	112	37.33
Nationality		
Saudi	297	99.00
Non-Saudi	3	1.00
Marital status		
Married	262	87.33
Unmarried	38	12.67
Education		
Educated	194	64.67
Non-educated	106	35.33
Employment		
Employed	44	14.67
Unemployed	256	85.33
Age		
Median age (range)	53.62 (42.22 – 64.01) years	

Correlation between demographics and interest in participation in CR

Assessment of respondent's familiarity with clinical research showed that most of them (289, 97.31%) did not know about IRB. Respondents who were previously asked by their physicians, and those who previously participated in clinical studies represented 15 (5.05%) and 17 (5.72%) respectively.

Univariate analysis was applied to study the correlation between demographic characteristics of respondents and their interest in participation in clinical trials.

Table 2 showed the significant correlations that were found between respondent's interest in participation and both age (>45 and ≤45) and education (educated and not educated), with p values 0.0127 and 0.0225 respectively.

Table 3 showed the multivariate analysis which revealed that younger patients (>45 years) are two time more likely to be willing to participate in CR (OR 1.995 with 95% CI 1.153-3.451), and showed the significance of education as a predictor for participation in CR.

Table 2: Univariate analysis for respondent's interest in participation in CR (n=300).

Variables	Interested		Not interested		P value
	Count	Percentage (%)	Count	Percentage (%)	
Gender					
Female	140	74.47	48	25.53	0.6529
Male	86	76.79	26	23.21	
Nationality					
Saudi	225	75.76	72	24.24	0.0904
Non-Saudi	1	33.33	2	66.67	
Marital status					
Married	200	76.34	62	24.12	0.2910
Unmarried	26	68.42	12	31.58	
Education					
Educated	138	71.13	56	28.87	0.0227
Non-educated	88	83.02	18	16.98	
Employment					
Employed	30	68.18	14	31.82	0.2343
Unemployed	196	76.56	60	23.44	
Age in years					
>45	166	79.43	43	20.57	0.0129
≤45	60	65.93	31	34.07	

Table 3: Multivariate analysis for respondents' interest in participation in CR (n=300).

Compared Variables	Crude OR	95% CI	P value
Gender			
Females vs. males	1.134	0.656 to 1.961	0.6525
Nationality			
Saudi vs non-Saudi	6.250	0.559 to 69.945	0.1370
Marital status			
Married vs unmarried	1.489	0.710 to 3.124	0.2925
Education			
Educated vs non-educated	0.504	0.278 to 0.914	0.0239
Employment			
Employed vs unemployed	0.656	0.327 to 0.317	0.2359
Age in years			
>45 years vs ≥45 years	1.995	1.153 to 3.451	0.0136

Table 4: Respondent's answers to survey questions.

What are the factors that positively influence your participation in a clinical trial?	Count	Percentage (%)
My advanced disease level affects my decision to participate	260	86.67
I had no other treatment option	256	85.33
I may have a better chance of being cured	211	70.33
I trust the doctor treating me	210	70.00
The doctors want me to join the clinical trial	116	38.67
My family wants me to join the clinical trial	77	25.67
Trial results offer help to other patients	60	20.00
I may receive more detailed information (toxicity/safety) about my treatment on the clinical trial	35	11.67
I might receive better care on the clinical trial	32	10.67
My doctor offers enough time to listen to all my questions	27	9.00
A clinical trial is the only way to receive the effective treatment	25	8.33
A clinical trial contains the best available treatment	17	5.67
Don't know why, just did it	7	2.33
Other reasons for joining the trial	00	00

Continued

What are the factors that prevent you from participation in a clinical trial?	Count	Percentage (%)
Fear of side effects	175	58.33
Unknown Efficacy of treatment	174	58.00
Preference for receiving standard treatment	168	56.00
Clinical trials are not appropriate for serious diseases like cancer	140	46.67
General discomfort with the research process	118	39.33
Fear of confidentiality breach	107	35.67
Not interested in clinical research	98	32.67
My family has up to date information about my clinical care	90	30.00
My family agrees with my current treatment plan	89	29.67
I may lose other medical care while I am in a trial	74	24.67
The doctor may seem more interested in the trial than me	73	24.33
Institutions, pharmaceutical companies or physicians have financial interest in clinical trials	70	23.33
I do not have enough time to participate in a clinical trial	69	23.00
A clinical trial may have a greater effect on my daily activities	53	17.67
A clinical trial may disturb my life at home	52	17.33
The doctor may not know as much about the treatment	37	12.33
Others	00	00

Positive influencing factors and barriers against participation in CR

Table 4 shows the analysis of respondent's answers to questions about the factors that can influence their participation in clinical trials, and the factors that can prevent them from participation as well.

DISCUSSION

Our study revealed that although very few participants were aware of clinical trials, the majority (75.33%) showed interest in participation in CR, if offered, which reflects that our respondent's interest in participation in CR did not essentially depend on their awareness of CR. These results differ from those obtained by Bazarbashi et al. in Saudi cancer patients between December 2011 and February 2013, where (58%) of the participants were aware of clinical trials, while (61%) showed their interest in participation in CR; which may reflect that those patient's willingness to participate in clinical trials depended largely on their awareness of CR.[16] Our results also differ from those obtained by Comis et al where approximately 32% of American adults (64 million individuals) expressed their willing to take part in cancer clinical trials if offered, and from those obtained by Khalil et al where the majority of Egyptian respondents indicated that they would not participate in research that involved more than minimal risk.[19,2] However, the comparison is not accurate since our respondents were all cancer patients, while participants of these two studies were not essentially patients which may reflect their fear of being exposed to such trials with no need.

Univariate analysis followed by multivariate analysis for our respondents revealed that patients younger than 45 years and those who received education were significantly more interested in participation in CR. These results are similar to those obtained by Ellis et al who found that younger participants were more likely to consider participation in CR, and those obtained by Baquet et al who found that respondents who received high education were significantly more likely to be recruited in clinical trials.[4,13] Such similar results among different populations point to the importance of education regarding the awareness of and inclination to participate in clinical trials, and highlights that younger generations have higher levels of awareness of CR.

The most common factors found to influence the willingness of patients under study to participate in CR were patient's advanced diseases (86.67%), and the absence of other treatment option (85.33%), followed by the probability of having a better chance of being cured (70.33%), and trust in treating physician (70%), while the factor of "doctors want patients to join clinical trials" accounted for (38.67%). These results differ from those obtained in Wales, United Kingdom by Jenkins et al who found that the primary reason given for trial acceptance among their studied population was altruism (40%). This may reflect the different cultures of the two populations.[1]

Our study revealed that the most common barriers found to hinder participation in clinical trials were fear of side effects (58.33%), and unknown efficacy of treatment (58%), followed by preference for receiving standard treatment (56%), and the belief that clinical trials are not appropriate for serious disease (46.67%), while general discomfort with the research process represented (39.33%). In a similar study conducted between September and November 2015 in two different tertiary level hospitals (King Khalid University Hospital and King Fahad Medical City Hospital) in Riyadh, Saudi Arabia, Almutairi et al classified barriers that prevent participation in CR into patient- and physician- related barriers. Patient related barriers included limited awareness, misconception, and fear, while a physician

related barrier was found to be the lack of encouragement from physician to patients in participating in a CT.[18] In a systematic review that was carried out to assess studies of barriers to participation in CR for validity and content, Mills et al found that the most factors referred to as barriers were worries about research setting, the existence of a placebo group, complexity of the process, fear of potential side effects, the belief that clinical trials are not appropriate for serious disease, a dislike of randomization, uncertainty of trial opportunities, overall discomfort with the trial process, and fear of potential negative effect with the physician upon enrolment in the trial.[20] In another systematic review in which Tournoux et al identified 75 papers published up to August 2004 that reported barriers to patient's participation in CR, the barriers were found to be worries about data and consent, uncertainty, and relationship with the research team.[3] The similar barriers among different populations reflect the common concerns of cancer patients all over the world, and call for developing strategies to raise awareness of clinical research and thus relieve patient's participation decisions related stress, which will improve their attitudes toward CR, and lead in turn to higher enrolment rates.

Our study has a limitation which is being conducted at one institution which in turn may have led to the unavailability of different clinical trials that suit the respondent's cases.

CONCLUSION

The awareness level of participants about CR is not satisfactory, and thus a higher level of awareness is required, which needs a lot of efforts from Contract Research Organizations (CROs) and healthcare providers involved in CR. However, there is an obvious interest in participation in CR especially in younger patients and those who received education.

Recommendation

We recommend that healthcare regulatory bodies, different CROs, and CR certifying bodies incorporate some educational materials about the importance and methods of raising the awareness of patients about CR in Good Clinical Practice (GCP) trainings and certification programs. Moreover, we recommend that hospitals and clinics develop strategies to encourage patients, and healthy people who visit them for screening/checkups to participate in CR.

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