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Willingness of a Sample of Health Professionals to Participate in Clinical Research as Research Subjects

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Abstract— **Background: Saudi Arabia has recently become more devoted to clinical research, which remains a relatively new and challenging area for researchers. Recruiting individual subjects in clinical research is believed to be an essential element in clinical trial success and is intensely dependent on the potential willingness of subjects to participate in clinical trials.**

Methods: A cross sectional study of a purposive sample of 323 health professionals was conducted. The study participants included students of Nursing and Medical College, physicians, nurses and paramedical personnel. A validated questionnaire assessing the willingness to participate, motives, obstacles was used.

Results: In general, about 80% of the participants were willing to participate in clinical research. The highest percentage of willingness to participate was reported when participants were asked about their willingness to answer questions in surveys (90.7%). Nearly 80% of participants considered getting a free medical tests and appointments as important intensives whereas 69.8% supported financial incentives to be efficient in encouraging people to participate in clinical research. Weak positive though significant correlation was detected between level of trust in the research institute and willingness to participate in clinical research.

Conclusion: Overall, this study confirmed that the decision for participation in research is closely related to the nature of the clinical trials, people usually welcome participation in questionnaires and noninvasive studies but their concerns are major when deciding for their children. Saudi community favors the free medical services to financial aids as incentives to participate in research trials.

Index Terms **: Acceptance, clinical trial, research subjects, willingness.**

I. Introduction

Saudi Arabia has recently become more devoted to clinical research, which remains a relatively new and challenging area for researchers. Recruiting individual subjects in clinical research is believed to be an essential element in clinical trial success and is intensely dependent on the potential willingness of subjects to participate in clinical trials [1]. Previous literatures have recognized many contributing factors of the potential willingness of participants to join research trials including, age[2] race [3], and various personal reasons[4].

Rejection to join clinical trials may be due to worries about drug side-effects, busy lifestyles, distrusting physicians or institutes conducting the research. Furthermore, significant decisions, such as participation in clinical trials, are expected to be more challenging if one is going to decide for his children.[5]

The nature of the clinical trial itself is a possible factor that can influence a subject's decision to participate or to decline involvement in clinical research. Participation in a clinical trial that involves new drugs differs from trials that merely require answering questionnaires. However, the ability of researchers to explain to participants the nature of the trial, and possible drawbacks along with participants 'trust in the researchers and the research institute, can play a crucial role in participant's decision .[6-8].

This study's aim is to identify the willingness of health professionals towards being a research subject and to investigate the different barriers and motivations that may help in recruiting patients in clinical trials.

II. Subjects and Methods:

A cross sectional study of a purposive sample of 323 health professionals was conducted. The study participants included students of Nursing and Medical College along with physicians, nurses and paramedical personnel. The study was conducted in King Abdul-Aziz Medical City and King Saud bin Abdul-Aziz University for Health Sciences after approval from the scientific research committee (RC12/109/R).

All participants were invited to complete the pretested questionnaire after giving a verbal consent to participate in the study.

The first section of the questionnaire inquired about demographic data as age, gender, nationality and occupation. The second section of the questionnaire assessed the willingness to participate in clinical trials. This section was derived from a validated published study[9]. It included one general question about willingness to participate in clinical trial as a research subject. Other specific questions examining willingness to participate in different clinical studies as completing surveys or giving blood/urine/ saliva samples were included. More questions examining the willingness to participate in different clinical trials as; diet program, new drugs for treating hypertension and study for surgeries in cancer were incorporated. The answers for these questions were available on a 10-points scale where "One" represents "I would never participate" and "Ten" represents "Very willing to participate". The scores for answers were grouped into two categories; unwilling to participate (scores 1 to 4) and "willing to participate" (scores 5 to 10 inclusive).

Participants were required to evaluate the importance and

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relevancy of possible incentives and obstacles to enroll in clinical trials on a scale of 1 to 10. Possible incentives included financial aids, free medical services or free medical investigations. Speculated reasons for refusal included; lacking the interest, fear of side-effects/ complications, unclear explanation of the clinical trials and mistrust in researcher/institute. The importance/relevance score was grouped into two groups; unimportant/irrelevant (scores 1 to 4) and important/relevant (scores 5 to 10)

Questions testing level of trust in the medical institute conducting the clinical trials especially confidentiality and treatment of any possible side effects were added. Four points were assigned to answer "strongly agree" and one point "strongly disagree". Cronbach's alpha for the trust items was 0.78.

The questionnaire was piloted among 25 volunteers to test its validity as well as feasibility and clarity of questions. Modifications were conducted accordingly. Cronbach's alpha for willingness to participate items was 0.80.

Statistical analysis was conducted using SPSS version 16. Descriptive statistics in terms of average, standard deviation, numbers and percentages were used. Inferential statistics as t-test and chi-square tests were used as appropriate. Pearson correlation coefficient was used to test correlation between quantitative variables. P-value less than 0.05 was considered statistically significant..

III. RESULTS

Three hundred and fifty health professionals were invited to participate in the current study, among which 323 participants accepted to join the study (response rate 92.3%). The average age was 30.1±10.9 years and the majority was female 84.5% (273) and about 60% were Saudi. Medical and nursing students represents 37.7% of participants, nurses were 32.3%(103), paramedical personnel constituted 31.1% and only six physicians (1.9%) participated in the study. Seventy participants (21.7%) had already participated in clinical research as researchers. Previous bad experience in clinical research was reported by 11.6% (37) of participants.

Table1 shows the willingness to participate among the studied sample. In general, about 80% of the participants were willing to participate in clinical research. The highest percentage of willingness to participate was reported when participants were asked about their willingness to answer questions in surveys (90.7%). Regarding participation in clinical trials; trials involving losing weight shows the highest potential willingness (80.7%) to participate, however, the least percentage of willingness to participate (63.2%) was recorded when the participant is requested to try a new treatment for diseases as hypertension. Giving biological samples as blood (85.1%), urine (82.0%) and sample of saliva (78.0%) were highly reported. The percentage of participants who are willing to let their children to participate in a clinical research was 60.8%.

Nearly 80% of participants considered getting a free medical tests and appointments as important intensives whereas 69.8% supported financial incentives to encourage people to participate in clinical research (Table 1).

Being afraid/worried of the side effects/complications was rated as the most relevant reason for refusal to participate in the clinical research (87.2%), followed by lacking sufficient information about the nature and outcomes of the study (79.5%) whilst the least relevant treason as perceived by the studied sample was being skeptical about the importance of clinical research (50.8%)

Table 1: Willingness to participate in clinical research among the studied sample

Willingness to participate in clinical research	**Willing N (%)**	**Not-willing N (%)**	**willingness X±SD**
1. How willing would you be to participate in clinical research studies in general?	255(79.9)	64(19.8)	6.4±2.6
2. How willing would you be to participate if you only had to answer questions in a survey?	291(90.7)	30(9.3)	7.7±2.4
3. How willing would you be to participate in a clinical research studying weight loss by following a special diet?	260(80.7)	62(19.3)	7.2±3.0
4. How willing would you be to participate in a clinical research studying new treatment for hypertension?	204(63.2)	119(36.8)	5.7±3.1
5. How willing would you be to participate in a clinical research studying new surgery for cancer?	225(69.9)	97(30.1)	6.1±3.2
6. How willing would you be to participate if you had to give a blood sample?	275(85.1)	48(14.9)	7.6±2.8

7. How willing would you be to participate in a study if you had to give a urine sample?	259(82.0)	57(18.0)	7.3±2.9
8. How about a sample of saliva?	252(78.0)	71(22.0)	7.0±3.1
9. If you are taking the decision for your son/daughter, how willing would you be to let him/herparticipate in a clinical research study?	194(60.8)	125(39.2)	5.3±3.0
Incentives to participate in clinical research	**Important N (%)**	**Unimportant N (%)**	**Importance Average ±SD**
1. How important would be getting a free medical test/appointments as a reason for you to participate?	260(80.7)	62(19.3)	6.9±2.9
2. How important would be getting paid money as a reason for you to participate?	224(69.8)	97(30.2)	6.1±2.7
Reasons for refusal to participate in clinical research	**Relevant N (%)**	**Irrelevant N (%)**	**Relevancy Average ±SD**
1. He/she has busy life and no time to participate.	239(74.5)	82(25.5)	6.1±2.7
2. He/she is afraid of the side effects of treatment.	280(87.2)	41(12.8)	7.5±2.7
3. He/sheis skeptical about the clinical research.	163(50.8)	158(49.2)	4.5±2.9
4. He/shedistrust the researcher and/or the organization.	234(72.9)	87(27.1)	5.9±2.7
5. Information provided about the research was unclear or complicated.	256(79.5)	66(20.5)	6.6±2.8

*Some questions were not answered by all participants.

Table 2 summarize the relation between various factors that might affect the willingness to participate in clinical research in general as gender, occupation and history of working as a researcher or having any unpleasant experience. No statistical significant difference was detected between males versus females or among Saudi and Non-Saudi regarding Participation in clinical research generally. However, physician showed more potential willingness to participate in clinical research (p=0.03) compared to students, nurses and paramedical personnel. Participant who had worked as researchers showed more willingness to participate in all types of researches (p=0.01) even when taking decision for their children participation (p=0.03). Females were more conservative when taking the decision for their children when compared to males (Table II).

Table 2: Factors influencing willingness to participate in clinical research

	Participation in clinical research Average± SD	**P-value**	**Participation of children Average± SD**	**P-value**
Gender				
Males	6.5±2.9	0.94	6.2±3.0	0.02
Females	6.4±2.6		5.1±3.0	
Nationality				
Saudi	6.6±2.7	0.25	5.0±3.2	0.05
Non- Saudi	6.2±2.5		5.7±2.7	
Occupation				
Students	6.6±2.9	0.03	4.8±3.1	0.10
Nurses	6.0±2.4		5.5±2.7	
Physician	8.8±1.3		6.0±2.5	
Paramedical	6.6±2.5		5.7±3.2	
History of working in research				
Yes	7.3±2.3	0.01	6.0±3.0	0.03
No	6.2±2.7		5.1±3.0	
History of unpleasant experience with clinicalresearch				
Yes	6.1±2.9	0.51	6.1±3.1	0.61
No	6.4±2.6		6.1±2.9	

The total trust scores have an average of (9.2±1.8), the

minimum was 3 points and the maximum was 12. A weak positive though significant correlation was detected between level of trust and willingness to participate in clinical research (r=0.14, p=0.01) (Figure 1).

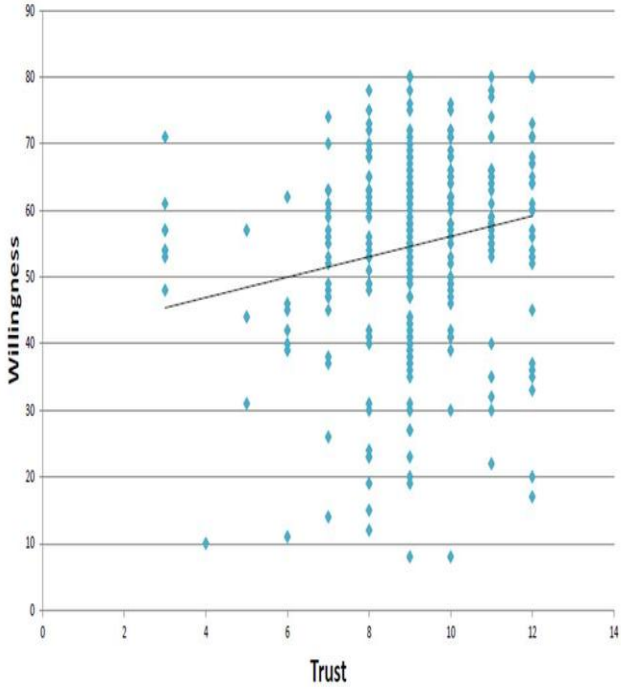

Figure 1: Correlation between the level of trust and the willingness to participate in research

IV. Discussion

Achieving greater rates of participation in clinical trials is a great concern for nearly all researchers and to our knowledge no previous studies have addressed the willingness to participate in clinical research among Saudi.

In the current study, the potential willingness to participate in different clinical studies was relatively high with the highest willingness reported to participation in surveys(90.0%). Researches requiring collection of biological samples were obviously welcomed but to a slightly lower extent (85% for blood samples and 78% to give saliva samples). These findings are more optimistic than those found by Al-Amad et al [10] who investigated the attitude of dental patients towards research and found out that 81% of them were willing to participate in questionnaire based studies and only 51% were willing to give salivary samples. The current results are consistent with another study involving in-depth interviews of Egyptians, which also confirmed that, most participants found studies involving less risky interventions (e.g. surveys), are more likely to be acceptable[11].

A considerable percentage of the studied population (about 70%) were very willing to participate in clinical trials related to cancer , which exceeds figures reported by Comis et al [6], where about 32% of adult Americans were willing to enroll in cancer clinical trials. Another study assessing the participation rate of cancer patients in clinical trials found out that only 39 patients out of 276 accepted to participate (an overall rate of 14%) and (37/76, 49%) declined trial participation despite meeting eligibility criteria.[12]

More than 80% of respondents were willing to participate in trials of diet control which is greater than those willing to participate in other kinds of suggested trials (hypertension and cancer) that can be explained by the global trend of controlling weights and body shaping. Moreover, this finding surpasses that revealed by Durant et al [7] who studied the willingness to participate in three different clinical scenarios among Americans who had previous experience with research of whom ,about 53% were willing to join diet control trials.

These optimistic figures of the potential willingness to participate in research in this study are justifiable, as the studied sample is quite knowledgeable about researches and can clearly appreciate the value of scientific researches.

The least reported willingness (around 60% of participants) was observed when someone is making his/her decision for his/her children; additionally, females were much more hesitant to permit their children to be research subjects. These finding are in accordance with another study which found that nine out of eleven participants who showed high concerns about children participation in research were women.[11] Another study affirmed the difficulty to accept enrolling of children in research especially if it requires blood sampling [13] .Children are key group who are commonly underrepresented in clinical research which results in inferential errors and bias in some trials.

The influence of personal benefit on participation in a clinical research is a natural human trend and has been confirmed in many studies[14],[15]. It can be through accessing free medical services or getting latest treatments or monetary incentives. The present results showed that the likelihood of earning a financial incentive was not very welcomed when compared to free medical services (70% compared to 81% respectively). The issue of payments to encourage individuals to participate in clinical research is debatable. Some individuals may consider paying the participants as a pressure rather than incentive whilst others would prefer it even more than offering free medical services.[16],[17]

In 2010, according to United Nation; the total population size in Saudi Arabia was 27,258 of which about 30% are immigrants.[18] Contrary to studies which have highlighted the lack of participation in clinical trials among minorities or ethnic groups [19-21], Saudi and Non-Saudi participants in this study did not show significant difference in their willingness to participate in clinical research. Furthermore, Non-Saudi were more willing to let their children to participate in research. This discrepancy could be explained by the nature of the studied sample; as they are highly educated and working in the medical field which positively reflects on their attitude and views towards clinical research.

Ohmann and Deimling[22] stated that previous participation in a research was considerably associated with more willingness to participate in further research. The current study acknowledged this finding among researchers

and showed that participants who were involved in clinical trials as researchers are more willing to enroll in studies as research subjects.

In the current study, positive correlation was confirmed between trust in the institute conducting the research and the potential willingness to participate in clinical research. It has been well documented in international research that trust in researchers contributes significantly to participation in research, regardless of whether participants understand the study or not [7], [23] . Additionally, mistrust in physician and /or institute is definitely hindering the participation in research and is perceived as serious obstacle towards enrolling in clinical trials as declared by current participants and from other studies as well.

There is plenty of subjective information on what prevents subjects from participating in research. Participants were asked to speculate possible barriers of participation in research. As many other studies, Participants showed their concerns about possible side effects and risks associated with the clinical trials [8], they raised their worries about the mistrust in researchers and research institution [4],[7],[23],[24], and confirmed the importance of clear and informative explanation of the study purpose and protocol to potential participants[4],[8]

Finally, some limitations of the current study can be defined. The sample was a purposive type and hence their views might not reflect those of the general Saudi population. Secondly, the generalizability of the results may also be limited as the studied sample was health professionals who definitely comprehend the nature and importance of research more than others. However, this study gives a comprehensive view of health professionals who work very closely to the general population and are actively involved in research process. Hence; they are able to define various aspects of willingness of patients to participate in research and can correctly predict how Saudi patients would react if invited to enroll in research.

CONCLUSION

Overall, this study confirmed that the decision for participation in research is closely related to the nature of the clinical trials, people usually welcome participation in questionnaires and noninvasive studies but their concerns are major when deciding for their children. Saudi community favors the free medical services to financial aids as incentives to participate in research trials. Thorough explanation of the clinical trial and the trust in the research institute boost people willingness to participate in clinical research

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