

Knowledge and Attitudes Towards Clinical Trial Participation in Oman

A cross-sectional study

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معرفة وسلوك المرضى تجاه المشاركة في التجارب السريرية في عمان دراسة مقطعية

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ABSTRACT: Objectives: Clinical trials are prospective studies on human subjects designed to answer various clinical questions. However, only a limited number of clinical trials have been conducted in Oman. This study aimed to assess the knowledge and attitudes of Omani patients and their relatives towards participating in clinical trials. **Methods:** This cross-sectional study was conducted between October 2015 and March 2016 among 174 patients and relatives attending the Haematology and Oncology Outpatient Clinics and Day Care Unit of the Sultan Qaboos University Hospital, Muscat, Oman. A self-administered questionnaire was designed to elicit participants' knowledge of and attitudes towards participation in clinical trials. **Results:** A total of 100 patients and relatives agreed to take part in the study (response rate: 57.5%). The male-to-female ratio was 1:1.2. Only 31.3% of the studied population knew what clinical trials were and only 6.5% had themselves previously participated in a clinical trial. The majority agreed or strongly agreed that they would participate in clinical trials related to their own condition (59.2%). Overall, 89.7% expected to be informed about potential clinical trials by their treating physicians. **Conclusion:** Omanis had a low level of knowledge of clinical trials and a very low rate of previous participation in such trials, despite a moderate level of interest. Patients should therefore be educated and informed of ongoing clinical trials in order to improve participation rates for clinical trials conducted in Oman.

Keywords: Attitudes; Knowledge; Clinical Trials as Topic; Patient Participation; Oman.

المخلص: الهدف: التجارب السريرية هي دراسات مرتقبة مستقبلية على البشر مصممة للإجابة على أسئلة مختلفة تخص الطب السريري، بالرغم من ذلك، هناك ندرة في التجارب السريرية التي أجريت في عمان. هدفت هذه الدراسة إلى تقييم معرفة وسلوك المرضى العمانيين وأقاربهم تجاه المشاركة في التجارب السريرية. **الطريقة:** أجريت هذه الدراسة المقطعية بين أكتوبر 2015 ومارس 2016 من بين 174 من المرضى وأقاربهم الذين حضروا عيادات أمراض الدم والأورام ووحدة الرعاية النهارية بمستشفى جامعة السلطان قابوس في مسقط في عمان، تم تصميم استبيان لاستخلاص بيانات تتعلق بمستوى معرفة المشاركين وموقفهم تجاه المشاركة في التجارب السريرية. **النتائج:** وافق ما مجموعه 100 مريض أو أقارب مرضى على المشاركة في الدراسة (معدل الاستجابة: 57.5%). وكانت نسبة الذكور إلى الإناث 1:1.2. أظهرت النتائج بأن 31.3% من المشاركين لديهم معرفة مسبقة عن التجارب السريرية و 6.5% فقط كانوا قد شاركوا سابقاً في تجربة سريرية. وافق الأغلبية على أنهم سيشاركون في التجارب السريرية المتعلقة بحالتهم الخاصة (59.2%)، و 89.7% توقعوا بأن يكونوا على علم بأي تجربة سريرية محتملة من قبل الأطباء المعالجين. الخلاصة: كان لدى العمانيين مستوى منخفض من المعرفة بالتجارب السريرية ومعدل منخفض جداً من المشاركة السابقة في مثل هذه التجارب، بالرغم من وجود مستوى معتدل من الإهتمام. لذلك ينبغي تثقيف المرضى وإطلاعهم على التجارب السريرية الجارية من أجل تحسين معدلات المشاركة للتجارب السريرية في عمان.

الكلمات المفتاحية: سلوك: المعرفة؛ التجارب السريرية كموضوع؛ مشاركة المرضى؛ عمان.

ADVANCES IN KNOWLEDGE

- Omani patients and their relatives were found to have low levels of knowledge of clinical trials; however, there was a moderate level of interest in participating.

APPLICATION TO PATIENT CARE

- Making patients aware of clinical trials is likely to improve their knowledge of and participation in such trials. Based on the findings of this study, physicians in Oman should be encouraged to discuss the option of participating in clinical trials with patients when suitable. Moreover, information about ongoing clinical trials should be made accessible to patients at different hospitals.

A CLINICAL TRIAL IS A PROSPECTIVE STUDY of human subjects in which the effect of one or more interventions is compared with

a control group in order to answer important clinical questions.¹ It is a major type of investigative research methodology that assesses new interventions in order

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to provide non-biased insight into their effectiveness, as well as their potential adverse events and complications. The results of clinical trials are considered to constitute high-quality evidence in clinical medicine and have contributed to vast improvements in the quality of healthcare provision in various fields.²⁻⁴ However, according to the clinical trial registry of the National Library of Medicine (Bethesda, Maryland, USA), only 20 registered clinical trials to date have involved Oman, most of which were sponsored by various pharmaceutical companies.⁵

While patients' attitudes towards participating in clinical trials have been analysed in other areas of the world, they have not yet been studied in Oman; as such, the reasons underlying low clinical trial participation among the local population remain unclear.⁶⁻⁸ Various personal, sociocultural or religious factors may cause patients to be reluctant to participate in clinical trials. In addition, inadequate knowledge about clinical trials among patients, relatives and physicians, a lack of local expertise or previous experience in running clinical trials and limited funding, support and infrastructure may all act as barriers to participation.¹ Accordingly, in order to improve the status of clinical trials in Oman, it is important to understand patients' attitudes towards participation in such trials so as to identify areas for improvement. This study therefore aimed to assess the knowledge and attitudes of Omani patients and their relatives towards participating in clinical trials.

Methods

This cross-sectional study was conducted at the Sultan Qaboos University Hospital (SQUH), Muscat, Oman, between October 2015 and March 2016. A total of 174 adult patients and their relatives visiting the SQUH Haematology and Oncology Outpatient Clinics and the Day Care Unit were invited to participate in the study. Patients were excluded from the study if they refused to participate or were too sick to fill out the questionnaire. Based on assumptions of 10% accuracy and using a 95% confidence interval with a convenient sampling strategy, a minimum sample of 97 participants was deemed necessary.⁹ However, given the potential for missing data, the target sample size was increased to 100 participants.

A 48-item questionnaire to determine knowledge of and attitudes towards participating in clinical trials was designed based on an extensive literature review of questionnaires covering similar topics. New items were added and existing items were modified in order to conform to the local culture in Oman. The final version of the questionnaire included three domains. The first 11-item domain served to elicit

sociodemographic information about the subjects, including age, gender and disease characteristics. The second 14-item domain assessed participants' knowledge of clinical trials, with participants answering either "yes", "no" or "not applicable" to each question. The third 23-item domain consisted of a number of statements with which the participants were asked to rate their level of agreement. This domain covered various topics which might impact a participant's willingness to participate in a clinical trial, such as the blinded nature of a clinical trial, the random allocation of participants to intervention and control groups during the clinical trial, potential side-effects of the treatment used in the clinical trial and other factors influencing the decision-making process for clinical trial participation. Each item was scored on a five-point Likert scale using the responses "strongly agree", "agree", "neutral", "disagree" or "strongly disagree". All responses to the questionnaire were self-assessed by the participants, without the aid of physicians or nurses.

During the design of the questionnaire, an extensive literature review was performed to ensure that all areas related to the topic of clinical trial participation were included. Subsequently, an expert assessed the face validity of the content and design of the questionnaire. The items included in the survey were found to reasonably cover all important areas of assessment. The questionnaire was translated into Arabic and back-translated to English to ensure the semantic equivalence of the Arabic version.¹⁰ In order to remove any ambiguous items, the questionnaire was pilot-tested on 10 medical students and five of the participants of the full study. The reliability of all items in the second and third domains of the questionnaire was assessed using Cronbach's alpha (0.944).

Data were analysed using the Statistical Package for the Social Sciences (SPSS), Version 22.0 (IBM Corp, Armonk, New York, USA). Continuous variables were presented as means and standard deviations or medians and ranges, as appropriate. Categorical variables were presented as frequencies and percentages.

Ethical approval for this study was obtained from the Medical Research & Ethics Committee of the College of Medicine & Health Sciences, Sultan Qaboos University (MREC #1178).

Results

A total of 100 subjects agreed to participate in the study, with the remaining 74 declining due to time limitations or an inability to read and write (response rate: 57.5%). The mean age of the participants was 36 years (range: 17-71 years old) and the male-to-female ratio was approximately equal (1:1.2). Most of

Table 1: Sociodemographic characteristics of patients and relatives visiting the Sultan Qaboos University Hospital, Muscat, Oman (N = 100)

Characteristic	Percentage*
Gender	
Male	46
Female	54
Type of participant	
Patient	70
Patient's relative	28
Non-relative escort	1
Travel time in hours	
<1	38
1–2	26
>2	35
Place of residence	
Muscat	27
Al Batinah North	17
Al Batinah South	11
Al Sharqiya	8
Ad Dakhiliyah	20
Dhofar	6
Al Wusta	1
Al Dhahirah	9
Education level	
Elementary school	6
Secondary school	9
High school	35
Diploma	23
Bachelor's degree	21
Master's degree	2
Marital status	
Single	28
Married	62
Widowed/divorced	8
Monthly income in OMR	
<1,000	51
1,000–2,000	21
>2,000	7
Nature of illness	
Acute	21
Chronic	54
None	18

Main medical specialty involved	
None	6
Cardiology	1
Dermatology	2
Gastrointestinal	1
Internal medicine	2
Haematology	34
ENT	1
Psychiatry	1
Oncology	51

OMR = Omani riyals; ENT = ear, nose and throat.

*Percentages do not add up to 100% due to missing data.

the participants were patients (70%) and resided in Muscat or Ad Dakhiliyah (27% and 20%, respectively). Their travel time varied, with 38% travelling less than one hour and 35% travelling more than two hours to arrive at SQUH. The majority of patients had been educated to a high school level or higher (81%). Approximately half of the participants had a monthly income of less than 1,000 Omani riyals per month (51%). The majority of the participants suffered from a chronic condition (54%), most of which were related to the medical subspecialties of oncology (51%) or haematology (34%) [Table 1].

In terms of their knowledge regarding clinical trials, only 31.3% and 31.6% of the participants knew what clinical trials were and why they were conducted. Very few of the participants had previously participated in clinical trials (6.5%). Just under a third of the patients knew that clinical trials were experiments on human subjects (32.6%). Few of the participants thought that there was risk involved in clinical trial participation (16.3%). Of the participants, 66.3% knew that clinical trials were ethical, 70.5% were aware that clinical trials were beneficial to society and 71.4% knew that clinical trials were critical for the advancement of medical care and knowledge. Most of the participants (66.7%) thought that the Omani government should allow pharmaceutical companies to conduct clinical trials, with 62.3% aware that such companies would require governmental approval prior to conducting a trial. Many participants (33.7%) had found out about clinical trials from their medical care professionals, whereas 32.9% had read about them on the Internet. Mass media and other patients were the least frequent sources of information about clinical trials (31% and 14.9% of participants, respectively) [Table 2].

With regards to their attitudes towards and willingness to participate in clinical trials, 59.2% of the participants either agreed or strongly agreed that they would participate in clinical trials related to their

Table 2: Knowledge of clinical trials among patients and relatives visiting the Sultan Qaboos University Hospital, Muscat, Oman (N = 100)

Questionnaire item	Percentage	
	Yes	No
Do you know what clinical trials are?	31.3	68.7
Do you know why clinical trials are conducted?	31.6	68.4
Have you participated in clinical trials before?	6.5	93.5
Is a clinical trial an experiment on humans?	32.6	67.4
Do you think that clinical trials benefit society?	70.5	29.5
Are clinical trials ethical to conduct?	66.3	33.7
Is there risk involved in participating in a clinical trial?	16.3	83.7
Is it necessary for a company to get approval from the government to conduct a clinical trial?	62.3	37.7
Are clinical trials critical to advance medicine and improve therapy effectiveness?	71.4	28.6
Should pharmaceutical companies be allowed to conduct clinical trials in Oman?	66.7	33.3
Did you find out about clinical trials from physicians or medical professionals?	33.7	66.3
Did you find out about clinical trials from mass media?	31	69
Did you find out about clinical trials from the Internet?	32.9	67.1
Did you find out about clinical trials from other patients?	14.9	85.1

condition. Most patients either agreed or strongly agreed that they would not mind being contacted regarding clinical trials by phone (57.3%) or e-mail (42.7%). Of the participants, 38.5% either agreed or strongly agreed that they did not mind the randomised nature of allocation to a study group in a clinical trial, while 33.4% of the cohort either agreed or strongly agreed that they did not mind participating in a blinded trial. However, 32.1% were unsure if they would participate in a clinical trial if the treatment involved had potential side-effects. Nevertheless, the majority of the participants either agreed or strongly agreed that they would want to be informed of the results of the clinical trial in which they had participated (84.6%).

The vast majority of participants either agreed or strongly agreed that they expected to be informed by their doctors about ongoing clinical trials related to their medical condition (89.7%). Moreover, most participants agreed or strongly agreed that clinical trials

conducted at SQUH would likely follow both safety (86.1%) and privacy (79.5%) precautions. However, 47.7% of participants either agreed or strongly agreed that clinical trials sponsored by pharmaceutical companies were likely to result in a conflict of interest. More than half of participants either agreed or strongly agreed that most current treatments in medicine were based on evidence from clinical trials (53.5%). Just over half of the participants indicated that they would involve a family member in their decision as to whether to participate in a clinical trial (50.6%).

Factors which positively influenced willingness to participate in a clinical trial included recommendations by a treating physician (61.2%) and the ineffectiveness of current therapy (59.3%). Just under half of the participants indicated that a negative perception of clinical trials would not alter their decision to participate in a trial (49.4%). Similarly, 44.1% either agreed or strongly agreed that the unconfirmed nature of treatment in a clinical trial would not affect their decision to participate. Lastly, 14% strongly agreed and 45.3% agreed that they would be more likely to participate in clinical trials focusing on complementary or alternative medicine [Table 3].

Discussion

The results of the current study revealed that most Omani patients and their relatives had a low level of knowledge about clinical trials. This finding was to be expected, given the generally low number of clinical trials conducted in Oman.⁵ Other countries in the region have reported a low level of knowledge and awareness concerning clinical trials in similar populations.¹¹ A study from India also reported that only 40.2% of participants knew what clinical trials were.¹² Local awareness of clinical trials and the rationale for such research can be improved, potentially leading to higher rates of participation. To this end, patients in Oman should be kept informed of ongoing clinical trials, perhaps via posted advertisements in local hospitals and on social media platforms.

In the current study, a very low proportion of the surveyed patients and relatives had previously been enrolled in clinical trials. Nair *et al.* observed that only 0.5% of all clinical trials conducted worldwide included participants from the Middle East and North Africa.¹³ This finding is discouraging and may reflect various barriers to clinical trial participation in the region, such as poor infrastructure, low expertise, lack of funding and patient reluctance. Nevertheless, the majority of participants in the present study believed that clinical trials were beneficial to society; this is consistent with findings from Balasubramanian *et al.*'s study, in

Table 3: Attitude towards clinical trials among patients and relatives visiting the Sultan Qaboos University Hospital, Muscat, Oman (N = 100)

Item	Percentage				
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
I would be interested in participating in clinical trials related to my medical condition	18.1	41.1	32.5	7.2	1.2
I find it appropriate for an investigator to contact me by phone to inform me of a research project	6.1	51.2	14.6	26.8	1.2
I find it appropriate for an investigator to contact me by e-mail to inform me of a research project	4.9	37.8	24.4	28	4.9
I find it acceptable to be allocated in a random fashion to receive either treatment or a placebo during a clinical trial	9.6	28.9	21.7	26.5	13.3
I find it acceptable to participate in a blinded clinical trial, knowing that both the participants and physicians often have no knowledge of which treatment arm the patient will be allocated to	2.5	30.9	29.6	25.9	11.1
Even if I was told that the treatment prescribed to me in a clinical trial had potential side-effects, I would still be interested in participating	8.3	27.4	32.1	22.6	9.5
It is important for me to be informed by the investigator about the results of the clinical trial in which I participated	31	53.6	11.9	2.4	1.2
I expect my treating physician to inform me about current clinical trials involving medical conditions related to me	41.4	48.3	5.7	3.4	1.1
All reasonable precautions to ensure my safety are likely to be taken in clinical trials conducted at SQUH	32.6	53.5	10.5	2.3	1.2
All reasonable precautions to protect my privacy are likely to be taken in clinical trials conducted at SQUH	36.1	43.4	15.7	3.6	1.2
Clinical trials sponsored by pharmaceutical companies are likely to have conflicts of interest	16.7	31	42.9	4.8	4.8
Most current medical treatments are based on evidence from clinical trials	7	46.5	36	8.1	2.3
I would not involve anyone else in my decision to participate in a clinical trial	4.8	27.7	30.1	27.7	9.6
I would ask my children/spouse/parents before I participated in a clinical trial	9.6	41	22.9	18.1	8.4
The availability of a new medical treatment not available outside of a clinical trial would influence my decision to participate in the trial	12.5	32.5	36.3	15	3.8
The idea of contributing to medical knowledge would influence my decision to participate in a clinical trial	8.4	37.3	32.5	18.1	3.6
I would participate in a clinical trial if my doctor recommended it to me	18.8	42.4	24.7	12.9	1.2
I would be more likely to participate in clinical trials if I was not benefitting from my current treatment	15.1	44.2	23.3	14	3.5
A negative perception of clinical trials would not influence my decision to participate in a trial	9.2	40.2	33.3	14.9	2.3
The unconfirmed nature of treatment would not influence my decision to participate in a clinical trial	4.8	39.3	32.1	20.2	3.6
The thought of having to come to hospital frequently would not influence my decision to participate in a clinical trial	8.2	37.6	30.6	18.8	4.7
Preferring standard treatment would not influence my decision to participate in a clinical trial	10.6	38.8	37.6	11.8	1.2
I would be more likely to participate in clinical trials if they focused on complementary/alternative medicine	14	45.3	25.6	12.8	2.3

SQUH = Sultan Qaboos University Hospital.

which the same sentiment was echoed by 54.5% of Indian patients.¹² Not unexpectedly, most participants agreed that clinical trials were ethical and that clinical trials conducted at SQUH (i.e. in a university hospital setting) would conform to necessary safety and privacy standards. A recent study from Saudi Arabia found that 48.7% of respondents believed clinical trials were conducted in an ethical manner.¹¹

A low percentage of participants in the current study believed that there was risk involved in participating in clinical trials. In comparison, 48.71% of Indian participants in Balasubramanian *et al.*'s study considered clinical trial participation to be risky.¹² The reason for this difference in results is unclear, especially as the level of knowledge of clinical trials in both cohorts was poor. Despite the potential risk of adverse events or side-effects, over one-third of the Omani participants in the present study reported that they would still be inclined to participate in a clinical trial. This finding could potentially be explained by expectations that clinical trial protocols would undergo rigorous review by various regulatory committees in order to ensure the participants' safety.

For the majority of patients worldwide, their main point of reference regarding medical treatments is their treating or family physician. In the present study, most participants were made aware of clinical trials by their treating physicians; moreover, the vast majority expected to be informed of relevant ongoing clinical trials by their physician and to be updated regarding the results of any clinical trials in which they had participated. A Korean study reported that 52% of oncology patients were informed of available clinical trials by their treating physicians and that 26.8% were willing to participate in clinical trials if such participation was recommended by their treating physician.¹⁴ In a study from the Mayo Clinic in the USA, most participants indicated that they expected their treating physician to inform them about ongoing clinical trials as a treatment option and that they would not be willing to participate in future clinical trials if the results of previous trials had not been disclosed to them.⁶

As is to be expected given the local culture, approximately half of the Omani participants in the present study were in favour of involving their family members when making decisions regarding their participation in clinical trials. In contrast, Lee *et al.* reported that only 24.1% of Korean participants would involve their family members before agreeing to enrol in a clinical trial.¹⁴ In the current study, the availability of a new treatment not available outside of a clinical trial was a strong influencing factor when it

came to choosing to enrol in a clinical trial. This is generally considered to be one of the major benefits of clinical trial enrolment. As reported by Madsen *et al.*, access to a new drug or diagnostic tool and a desire for enhanced monitoring are major influencing factors for clinical trial participation.⁷

This study had a number of strengths. To the best of the authors' knowledge, this is the first survey detailing the knowledge of and attitudes towards clinical trials among a cohort of Omani patients and relatives. Moreover, although the sample was small, the findings of this study could be used as a basis to further develop the questionnaire and to carry out more extensive surveys on this topic. Finally, as the study sample included participants from both haematology and oncology outpatient departments, the responses are likely homogeneous.

Nevertheless, the results of this study should be interpreted in the light of certain limitations. According to previous research, only 6% of eligible participants choose to enrol in clinical trials.¹⁵ In the researchers' personal experience, the majority of Omani patients who are invited to enrol in an actual clinical trial refuse to participate. As such, the favourable responses observed in the current study are likely attributable to response bias due to the social desirability of a positive response, especially considering that the survey instrument was distributed by members of the patients' treating team. Moreover, the items included in the questionnaire could have been further tailored to the participants as, for example, knowledge of terms like randomisation and study blinding may not have been clearly understood.

Conclusion

The current study found that Omani patients and their relatives had low level of knowledge of clinical trials. However, there was a moderate level of interest in participating in such trials, especially when participation was suggested by a treating physician. These findings should therefore be considered when developing initiatives to encourage clinical trial enrolment in Oman. Further research on Omani patients' and relatives' attitudes towards clinical trial participation is recommended.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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