



Knowledge, Attitude and Apparent Job Stress Among Clinical Research Associates working at Contract Research Organizations (CRO)in MENA Region during Covid-19.

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INTRODUCTION

The SARS-CoV-2 unique human coronavirus that causes coronavirus disease 2019 (COVID-19) was initially discovered in Wuhan, China, in December 2019 and the disease soon spread to every continent, on March 11, 2020, the World Health Organization declared it to be a global pandemic (Kamacooko et al., 2021). Around the world, the COVID-19 epidemic has had a disastrous effect on the economy, social environment, and healthcare system. High levels of posttraumatic stress disorder, anxiety, sadness, and other distressing symptoms have been brought on by COVID-19. Additionally, the quantity and quality of social ties have decreased, as have people's impressions of others' feelings of empathy. The demand for health services has significantly increased in the healthcare sector as a result of Covid 19. Anxiety, depression, and sleep disturbance are just a few of the psychiatric problems that Covid-19 harms (Ramdan & Sari, 2022).

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In MENA region, The findings reveal the first instance of COVID-19 symptoms in a 16-month-old Lebanese girl who had previously been healthy (Mansour et al., 2020). The first case recorded in Saudi Arabia on March 7, after increased physical distance and numerous preventive measures, such as switching to an online school system, rising numbers observed throughout the world. COVID-19 has a detrimental effect on the general population's psychological health as well, particularly on younger individuals and women. This effect is not limited to physical health. Numerous recent studies have found that the general



population experienced considerable levels of melancholy, anxiety, stress, and obsessive-compulsive symptoms throughout the epidemic. The overall population's risk of depression and anxiety was rather high as compared to mental health before COVID-19 (Alateeq et al., 2022).

Healthcare professionals experienced exceptional stress due to the coronavirus disease 2019 (COVID19) pandemic, including work pressure, job uncertainty, concerns for their personal and family safety, and exposure to patient deaths occurring at rates that were out of the normal. The COVID-19 epidemic has continued for more than a year, which raises worries about how it could affect healthcare employees' work goals, mental health (anxiety and depression), and occupational stress (burnout) (Sinsky et al., 2021).

Clinical research associate/clinical study monitor (CRA/CSM): Ensures adherence to clinical trial protocol, monitors study sites and records results in monitoring reports. Monitors the progress and conduct of the clinical trial to ensure the integrity of the data collected and the safety of the participants. Before performing study-related procedures, the reviewer compares the case report form (CRF) with the original and medical records, confirms that informed consent was obtained from each participant in a timely and appropriate manner, records and investigates adverse events to ensure they are properly recorded, documented and, where possible, communicated (St Germain & Good, 2018). Clinical trials need a variety of professionals in addition to the doctors who examine the effects of new drug therapies on volunteers to ensure that trials are carried out in accordance with ICH or other regulatory bodies' guidelines, such as the US FDA, HSA, TGA, MHRA, Saudi FDA, etc. One of these professionals is a clinical research associate (Commissioner, 2021).

A contract research organization (CRO), also known as a clinical research organization (CRO), is a type of service provider that offers support to the biotechnology and pharmaceutical industries through the provision of outsourced pharmaceutical research services (for both drugs and medical devices) (IQ, 2010). Traditional CROs provide clinical trial administration services, while laboratory CROs provide drug research, manufacturing, laboratory and bioanalytical services (D'Mello, 2022).

Challenges in conducting clinical trials during the Covid-19 pandemic include time constraints, drug reuse, information gaps and operational difficulties. Traditional drug



development and discovery can easily take a decade from target identification to critical phase III clinical trials. COVID-19 cannot be treated with this method because there is not enough time to do so. New drugs would not have gone through research and early development optimization for COVID-19 because SARS-CoV-2 is a novel virus. The time window for the therapeutic dose of treatment is not clearly defined due to the lack of information on the dynamics of the SARS-CoV-2 virus and the progression of the disease, which can lead to false data. Clinical operations can also present problems because they cannot be performed in home quarantine due to routine assessments that require close monitoring of the patient(Shi et al., 2021). Thus, clinical researchers experience stress and burnout, which can lead to staff turnover and slow, inefficient clinical trials (Florence, 2022).

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Global research has changed significantly as a result of the COVID-19 pandemic. Due to difficulties in conducting clinical trials during the pandemic, more than 2,000 trials registered on ClinicalTrials.gov have been terminated(Bassi et al., 2022). Managing clinical trials during a pandemic adds to the difficulty. The COVID-19 pandemic has brought this into focus, and as countries impose restrictions to prevent the spread of the virus, the continuation of clinical trials around the world has been thrown into uncertainty. Due to the worldwide lockdown that has been issued, the clinical research associates are unable to travel(Shiely et al., 2021). This study will measure the knowledge, attitude and job stress among CRA's of Contract Research Organizations (CRO)in MENA Region during Covid-19.

Keywords: *Clinical Researcher Associates, Job Stress, Covid-19, MENA*

METHODOLOGY

Clinical research associates working in the Middle East and North Africa region were emailed the questionnaire forms for this study, which was done utilizing an online questionnaire-based survey and generated using Google forms. A senior academic member reviewed and validated the questionnaire. There was no collection or storage of personal information, and only the lead investigator had access to the data. A minimum of one month was allotted for this process, and two to three reminders were sent out to complete the questionnaire. A total of 101 individuals responded to the survey and the sample population was selected using a convenience sampling technique and was questioned regarding their



demographic details (age, gender, years of practice, clinical specialty, working location), knowledge and attitude of CRA's towards covid-19 disease and the job stress were analysed. Responders who were CRAs employed by clinical research organizations in and near MENA met the inclusion criteria. Non-clinical research associates and incomplete surveys were the exclusion criteria.

RESULTS

TABLE 1 | Demographic characteristics of the participants (N = 101)

Variables	Frequency(n)	Percentage (%)
Gender		
Male	45	45
Female	56	56
Age Group		
Below 30 years	26	25.7
31-40 years	46	45.5
41-50 years	24	23.8
Above 50 years	5	5.0
Marital Status		
Single	23	22.8
Married	64	63.4
Others	14	13.9
Working Experience		
0-5 Years	29	28.7
06-10 Years	40	39.6
11-20 Years	26	25.7
> 20 Years	6	5.9
Travel Frequency		
Less than 25%	22	21.8
Between 25% to 50%	54	53.5
More than 50%	25	24.8

The Table 1 shows the demographic characteristics of participants of which 45 % were males and 56 % were females. The age group shows that most of the participants comes under the age group of 31-40 46% and the least participants were above 50 years constituting 5%. The majority of them 63.4%(n=64) were married and having 6-10 years of experience 39.6%(n=40). The travel frequency of clinical research associates shows that 53.5% were



rated the frequency of 25% to 50% while 24.8% recorded as more than 50% of travel frequency.

TABLE 2 | Clinical specialty of the participants (N=101)

Clinical Specialty	Frequency(n)	Percentage (%)
Surgery	18	17.8
Psychiatry	11	10.9
Radiology	8	7.9
Cardiology	37	36.6
Paediatric	44	43.6
Ophthalmology	19	18.8
Gynaecology	24	23.8
Gastroenterology	12	11.9
Oncology	33	32.7
Neurology	21	20.8
Dermatology	16	15.8
Urology	14	13.9
Rare / Genetic disease	34	33.7
Medical Device	13	12.9
Endocrinology	70	69.3
Haematology	2	2
Infectious disease	2	2
Hepatology	2	2
Dental	1	1
Osteopathy	1	1
Orthopaedics	1	1
/rheumatology		
Neonatology	1	1
Infectious disease	1	1
/virology		
Orthopaedics	1	1
Rheumatology	1	1

According to the table 2 of the clinical specialty of the participants, 69.3% (n=70) of them having Endocrinology specialty followed by paediatric specialty 43.6% (n=44) and cardiology 36.6% (n=37). The CRA will examine medicines for their efficacy, hazards, and benefits as part of their clinical trials to make sure they are safe for the intended purpose. They will likely be involved in all phases of the clinical study, including choosing an exploratory site and setting up, starting, running, and concluding the trial. They will work on both new and old medications.



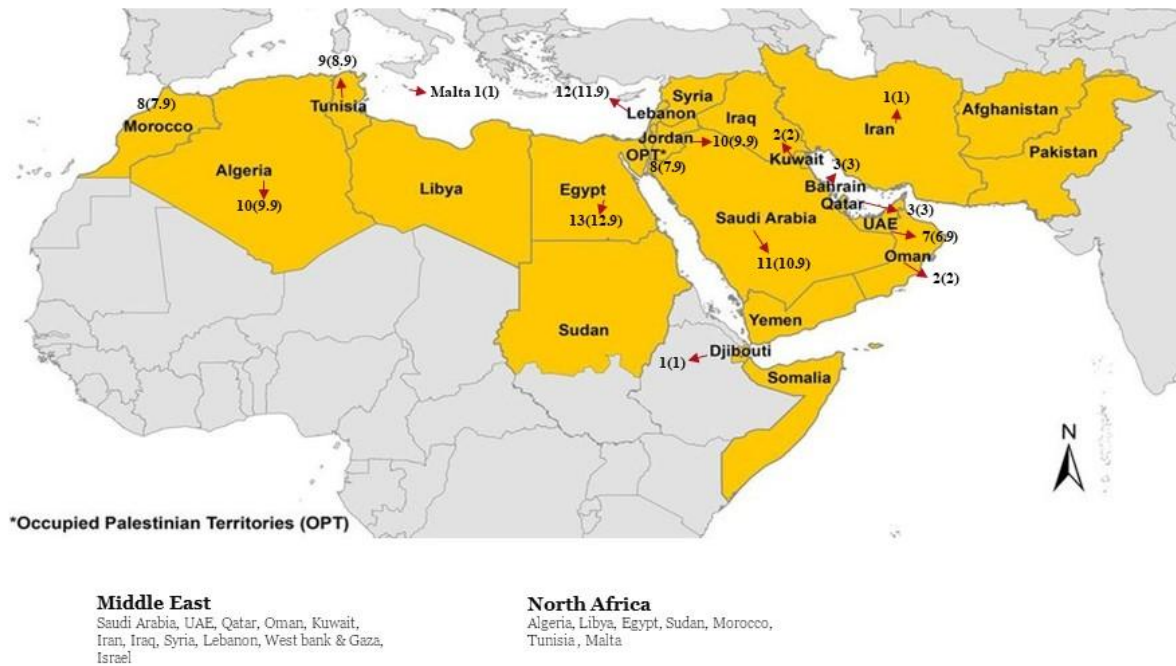


Figure 1: The working location frequency of CRA's in MENA region.

Figure 1 depicts the CRA's participated from Middle East and North African region. According to it, majority of them 12.9% (n=13) participants are hailing from Egypt followed by 11.9% (n=12) from Lebanon 10.9%(n=11) from Saudi Arabia. There is no data received from countries such as Syria, Libya, Sudan and Iraq as there is civil war going on and unable to contact the CRA's in that region.



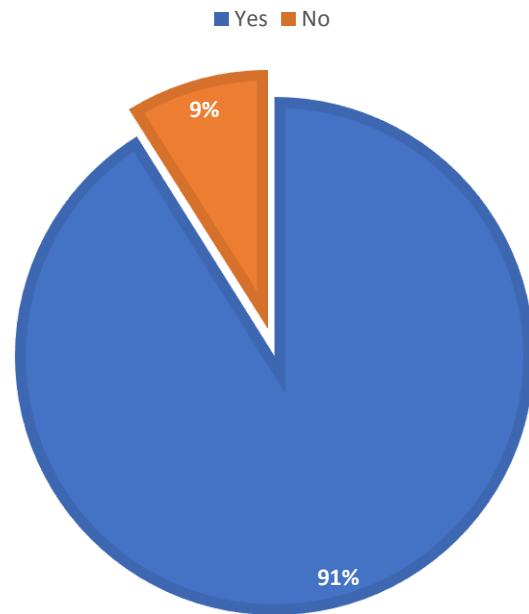


Figure 2: The prevention and safety training received by the respondents.

Figure 2 shows that 91% of CRA’s participated, received prevention and safety training for Covid-19 while 9% responded that they have not attended any trainings.

Table 3: CRA’s knowledge about covid-19

SL #	Factors	Strongly Disagree N (%)	Disagree N (%)	Neutral N (%)	Agree N (%)	Strongly Agree N (%)
1	The Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) are the same as Novel Coronavirus Disease (COVID-19).	2(2)	1(1)	0(0)	57(56)	41(40)
2	The COVID-19 incubation period lasts for 1 to 14 days.	1(1)	1(1)	1(1)	67(66)	31(30)
3	The COVID-19 spread by microscopic air droplets.	1(1)	1(1)	1(1)	68(67)	30(29)
4	There exists a COVID-19 vaccination or medication to treat it.	1(1)	0(0)	10(9)	56(55)	34(33)
5	The Antibiotics work well against COVID-19 and its complication	1(1)	2(1)	0(0)	64(63)	34(33)



6	Covid-19 training helps me to prevent the infections	0(0)	1(1)	6(5)	66(65)	28(27)
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In view of CRA’s knowledge about COVID-19, 56% (n=57) of them are that the severe acute respiratory syndrome (SARS) and Middle East Respiratory Syndrome (MERS) are the same as Novel Coronavirus Disease (COVID-19). The 66%(n=67) of the CRA’s agree that the COVID-19 incubation period lasts for 1 to 14 days. The majority of the CRA’s 63%(n=64) were aware that the antibiotics work well against COVID-19 and its complication. The 65% (n=66) agree that covid-19 training helps them to prevent the infections (Table 3).

Table 4: CRA’s attitude towards covid-19

SL #	Factors	Strongly Disagree N (%)	Disagree N (%)	Neutral N (%)	Agree N (%)	Strongly Agree N (%)
1	Frequent Handwashing techniques can stop the spread of COVID-19.	1(1)	1(1)	0(0)	57(56)	42(41)
2	I'm concerned that one of the family members might get an infection because I work in clinical research field and have frequent contact with clinical research team in sites and healthcare facilities.	0(0)	1(1)	2(2)	54(53)	44(43)
3	I believe the coronavirus poses a risk to our neighbourhood.	0(0)	1(1)	22(21)	56(55)	22(21)
4	I constantly worry that getting involved in healthcare facilities will expose me to COVID-19 sickness.	0(0)	2(1)	0(0)	52(51)	47(47)
5	Lack of awareness regarding the method of transmission and infection prevention techniques raises the risk of COVID-19.	0(0)	1(1)	1(1)	48(47)	51(50)

As per the table 4 given, CRA’s attitudes toward COVID-19, 56% (n=57) trust that frequent handwashing techniques can stop the spread of COVID-19. The CRA’s 47%(n=47) constantly worry that getting involved in healthcare facilities will expose them to COVID-19 sickness. This attitude always takes their stress level high as they were mostly involved in



healthcare facilities as part of the clinical research assignments. The majority 53%(n=54) were so concerned that one of the family members might get an infection because CRA's work in clinical research field and have frequent contact with clinical research team in sites.

Table 5: CRA's apparent job stress during covid-19 period.

SL #	Factors	Strongly Disagree N (%)	Disagree N (%)	Neutral N (%)	Agree N (%)	Strongly Agree N (%)
1	I have felt the effects of the epidemic, as though something significant will occur suddenly.	0(0)	1(1)	1(1)	73(72)	26(25)
2	Because of the epidemic, I have felt like I can't control the important things in my life.	0(0)	2(1)	1(1)	56(55)	42(42)
3	I have been anxious or stressed because of the Pandemic.	1(1)	1(1)	1(1)	52(51)	46(45)
4	I have felt overwhelmed by the tasks which I had to complete to prevent an infection.	0(0)	1(1)	1(1)	56(55)	43(42)
5	I have been upset that I have no control over the epidemic's effects.	0(0)	1(1)	4(3)	66(65)	30(29)
6	I have felt stress during travel due to restriction related to covid 19 protocols.	1(1)	0(0)	1(1)	43(42)	56(55)
7	I have felt stress due to new routine such as online and remote working atmosphere	1(1)	1(1)	7(6)	48(48)	44(43)
8	I have felt stress due to work efficiency and project risk management	1(1)	0(0)	2(1)	36(36)	62(61)

As far as the stress is concerned, due to the epidemic, the majority of CRA's 55%(n=56) agree that they can't control the important things in their life and also 45%(n=46) strongly agree that they were anxious or stressed because of the pandemic. Most of the CRA's 65% (n=66) agree that they were upset and have no control over the epidemic's effects 42%(n=43) agree that they were stressed during travel due to restriction related to covid 19 protocols. Most of the countries closed the airports to prevent the spread of covid-19 disease. The CRA's are more vulnerable to travel in and around the countries (Table 5).



DISCUSSION

Clinical research is now popular in areas that are still relatively unaccustomed to conducting trials since clinical trials have had such a significant impact on the world's scientific community. The Middle East and North Africa (MENA) area has seen the beginning of a new age in clinical research over the last several years (Abraham, 2011). Oil, gas, and petrochemicals are the main economic drivers in the MENA area, which is regarded as having one of the world's fastest expanding economies. As a result, there has been tremendous investment made in the healthcare sector, including the clinical research industry and cutting-edge hospitals that have the technology necessary to perform clinical trials (The World Bank, 2022).

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The local population's way of life has, however, undergone significant changes as a result of this economic expansion. This society has adopted a sedentary lifestyle, little physical activity, smoking, and an increasingly unhealthy diet. As a result, the MENA region is considered to be on the cusp of developing a number of ailments, including cardiovascular disease, genetic and hereditary diseases, endocrinology, cancer, etc. (Applied Clinical Trials, 2022)

To our knowledge, no detailed study had investigated CRA's knowledge, attitude and job stress during COVID-19 outbreak in MENA region. This research determines the job stress of CRA's especially in clinical research organizations in MENA segment. It was found that CRA's knowledge about COVID-19, the majority of the CRA's 63% (n=64) were aware that the antibiotics work well against COVID-19 and its complication and 65% (n=66) believe that covid-19 training helps them to prevent the infections. CRA's attitudes toward COVID-19, 56% (n=57) trust that frequent handwashing techniques can stop the spread of COVID-19. The CRA's 46% (n=47) constantly worry that getting involved in healthcare facilities will expose them to COVID-19 sickness. This attitude always takes their stress level high as they were mostly involved in healthcare facilities as part of the clinical research assignments.

As far as the stress is concerned, due to the epidemic, the majority of CRA's 55% (n=56) agree that they can't control the important things in their life and also 45% (n=46) strongly agree that they were anxious or stressed because of the pandemic. Most of the CRA's 65% (n=66) agree that they were upset and have no control over the epidemic's effects 43% (n=42) agree that they were stressed during travel due to restriction related to covid 19 protocols. The study had known limitations. First, it had the limitation of convenience sampling, which



affects the generalizability of the findings, but we increased the sample size to improve the representation of the sample by recruiting participants from MENA regions even though there exist civil wars in countries such as Iraq, Libya, Syria and Sudan. Secondly, using an online survey might limit our study, but it was a convenient method to reach the CRA's in different MENA countries. Thirdly, the sample includes only CRA's working in contract research organizations, which limits our study within these criteria.

There are drawbacks and stress associated with any job, but some are more difficult than others. Maybe it's the hard schedule, the impending deadlines, or just the fact that the work includes potentially fatal scenarios. However, it cannot be denied that some professions, despite being beautiful or emotionally satisfying, can be particularly demanding. Among those in this category are clinical research associates(Williams, 2022).



CONCLUSION

The aim was to assess the knowledge, attitude, and the job stress of clinical research associates working in contract research organizations during covid-19. The CRA's knowledge depicts that covid-19 training helps them to prevent the infections. The attitude shows that they were constantly worry that getting involved in healthcare facilities will expose them to COVID-19 sickness. The majority of CRA's agree that they can't control the important things in their life during the Covid-19 period. They strongly agree that they were anxious or stressed because of the pandemic and upset with the travel restriction related to covid 19 protocols. This study is limited to MENA region and further studies are needed for analysing the knowledge, attitude and job stress among CRA's in other regions.

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