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Cross-sectional Study on Occupational Stress of Clinical Research Associates in China

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Abstract

Background: There had been large amount of discussion and comments regarding the clinical research associate (CRA) work stress and quality of life in DXY, the primary website focusing on medicine and pharmaceutics in China. Quite a number of clinical research professionals described various examples and cases reflecting higher occupational stress of the Chinese CRAs. No relevant paper to date in the world have been formally published that assessing the CRA's workload or occupational stress. The purpose of the study was to investigate the occupational stress of the CRAs in China.

Methods: Chinese CRAs with more than 6 months monitoring experiences were enrolled into the study by convenient sampling. The number of participants from multinational CROs, local CROs, multinational pharmaceuticals and local pharmaceuticals were controlled to a ratio of approximately 4:3:2:1. A total of 200 CRAs were surveyed for work stressor, personal strain and coping resources by Occupational Stress Inventory Revised (OSI-R) Chinese edition during January to March 2013.

Results: Among the 178 participants evaluable, about 71.3% were females. Their average age was 28.76 years (SD=3.97 years), ranging from 21 to 42 years. 87.1% of the participants had a Bachelor's degree or above. Around 29.8% of the participants had medicine background, and 48.3% had pharmacy background. Role Ambiguity (RA) stressor was higher among the CRAs of age ≤ 25 years, while responsibility was higher among the CRAs of age ≥ 36 years age group. Vocational Strain (VS) was also higher among those of age ≤ 25 years. A trend of higher self-care resources was observed in elder CRAs and those of higher education levels. The CRAs from multinational CROs had highest coping resources.

Conclusion: This study revealed that the CRAs in China had moderate work stressor, personal strain and coping resources. The occupational stresses were varying amongst Chinese CRAs of different gender, ages, education levels and company types. The CRAs at age of ≤ 25 years had higher occupational stress than other age groups. The CRA's personal strain and its facets had their predicating factors, role insufficiency and role boundary were the main risk factors, while rational coping, recreation, social support and self-care were the protecting factors.

Keywords: Occupational stress; Clinical research associate; Occupational stress index-revised (OSI-R); Cross-sectional study; China

Introduction

In recent years, the clinical research business developed extremely fast in emerging countries such as China, India and Philippines, mainly because of increased high investigation fees in western countries. Specifically in China, an additional portion of drug applications falls under the area that requires bioequivalence study or clinical trials due to the amendment of the Drug Registration Regulation in 2007, including transition of dosage forms among injections, infusions and powder for injections, as well as new topical dosage forms [1].

The increasing numbers of clinical trials significantly promoted expansion of clinical research industry. At least 1,000 local and multinational Clinical Research Organisations (CROs), based on our knowledge, were involved in clinical trials monitoring in China by 2013, while the first local CRO was established only in 1997 [2]. As a major composite and revenue producer of a CRO company in which clinical research is its primary business, Clinical Research Associates (CRAs), have become one of the hottest figures in the Chinese talent market.

The CRAs or monitors are roles to ensure that the clinical trial is conducted and documented properly, acting as the contact window between sponsor and investigators, carrying out all monitoring activities where relevant and necessary to the trial and the trial sites [3,4]. In Europe and Americas, clinical monitoring had a history of up to thirty years, and the activities were well supported by laws and regulation [5,6]. The investigators and institutions operated under distinct structure and procedures relevant to clinical research, and could basically self-manage for subject enrolment, subject visit, data documentation and report [7,8]. The investigators or sub-investigators could focus on patient assessment and treatment, recording source document, while the Clinical Research Coordinators (CRCs) took up the other administrative activities such as investigator file management, IRB/EC submission and Case Report Form (CRF) entry [9,10]. It was usually the case that all documents and materials being prepared and ready for monitoring when CRA arrived at site. The monitor's job was recognised as a notable occupation without arisen of workload or stress concerns [11]. However there had been large amount of discussion and comments regarding the CRA work stress and quality of life in DXY, the primary website in China focusing on medicine and pharmaceutics [12]. Quite a number of clinical research professionals described facts and examples reflecting higher occupational stress of the Chinese CRAs. Those observations were mainly relevant to role loading, role insufficiency, role ambiguity, role boundary, responsibility and environment, which are the field of occupational stress research [13].

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For years now we have been aware of the problem of occupation stress among health care workers and the important specific risks that are linked to it for medical professionals. Studies had been carried out about the burnout of medical professionals, nurses, pharmacy technician, CRC, and other precarious employment [14-18]. Clinical monitoring is characteristic of responsibility, complication, time-effective and no-mistake, and the CRAs are likely to develop occupational stress when resource contest, extra burden, or insufficient training occurs. We conducted a literature survey and found no research published relevant to the CRAs occupational stress. Minimal work had been done among CRAs around the importance and insufficiency of clinical monitoring activities, and didn't consider the occupational stress status of the roles [19,20].

The goal of the study was to conduct a survey among Chinese CRAs to evaluate the status of occupational stress and explore the potential work stressors and coping resources.

Materials and Methods

Chinese CRAs with more than 6 months monitoring experiences were eligible to be enrolled in the study. Convenient sampling was used as random was not feasible due to business competition and confidentiality. In order to reflect the reality of the industry and based on our knowledge and peer's view, number of participants from multinational CROs, local CROs, multinational pharmaceuticals and local pharmaceuticals was controlled to a ratio of approximately 4:3:2:1.

A total of 200 CRAs were mailed electronic questionnaires and requested to self-administer all question items during January to March 2013. Incomplete questionnaires or those with discrepancies were queried immediately until all questions were answered sufficiently. Collected questionnaires with one or more missing items of the demographic information or more than 2.5% missing items from OSI-R were ineligible for analysis.

The Occupational Stress Inventory Revised (OSI-R) Chinese version was used in the study. The OSI-R was developed by Osipow for occupational stress assessment in 1981, and revised for seven times to the final version in 1998 [21]. It's now widely used in more than twenty countries as an occupational stress testing scale that provides a concise measure of three important dimensions of occupational adjustment: occupational stress, psychological strain, and coping resources [22]. The reliability and validity of OSI-R were tested in Chinese employment in 2001, and showed excellent performance after some of the items were modified [23]. The OSI-R is divided into three subsets, the Occupational Role Questionnaire (ORQ), the Personal Strain Questionnaire (PSQ), and the Personal Resources Questionnaire (PRQ). The ORQ consists of six facets as Role overload (RO), Role Insufficiency (RO), Role Ambiguity (RA), Role Boundary (RB), Responsibility (R), and Physical Environment (PE). The PSQ consists of four facets as Vocational Strain (VS), Psychological Strain (PSY), Interpersonal Strain (IS), and Physical Strain (PHS). The PRQ consists of four facets as Recreation (R), Self-care (SC), Social Support (SS), and Rational Coping (RC). Each facet is composed of ten questions, and there are totally fourteen facets to come up one hundred and forty items. Higher score of the ORQ and PSQ implies higher loading and stress, while higher score of the PRQ means higher coping capability.

The difference of occupational stress of CRAs were analysed among genders, age groups, education levels and company types. T-test was used for statistical comparison between two independent means. One-way ANOVA was used for analysis of multiple means, and further comparisons between each two-group were done by Student-Newman-Keuls with stepwise method. The influence of work stressor and coping resources on personal strain were evaluated through Pearson correlation and multiple liner regression analysis.

The occupational stress norm and classification criteria of a standardized Chinese employment developed by Yang [22] were utilized to compare the occupational stress of CRAs with standardized occupation [24]. The total score (T score) of each subset and item were converted by formula T score=50+10 × (Raw score –mean)×SD.

Results

182 CRAs responded and returned the completed questionnaires. Among the 178 participants evaluable, about 71.3% were females. Their average age was 28.76 years (SD=3.97years), ranging from 21 to 42 years. 87.1% of the participants had a Bachelor's degree or above. Around 29.8% of the participants had medicine background, and 48.3% had pharmacy background. The participants coming from multinational CROs and from local CROs were 41.6% and 33.1%, respectively. Descriptive statistics for demographic information are presented in Table 1.

The occupational stress in different genders was analysed. The vocational strain facet in personal strain subset in male CRAs was significantly higher than females ($P<0.05$). The self-care facet in personal resources subset in female responders was significantly higher than males ($P<0.05$). There was no difference in all other subsets or facets ($P \geq 0.05$). The means and standard deviation of the measured variables are presented in Table 2.

We tested the occupational stress in different age groups. In work stressor subset, the participants of age of ≤ 25 years obtained highest score for task ambiguity ($P<0.05$), while those of age ≥36 scored highest for responsibility ($P<0.05$). In personal strain subset, the vocational strain was highest in age of ≤ 25 group ($P<0.05$). In personal resources subset, the self-care facet score was highest in ≥ 36 years of age group.

Demographic characteristics	N	%
Gender		
Male	51	28.7
Female	127	71.3
Age group,year		
≤25	41	23.0
26-30	86	48.3
31-35	40	22.5
≥35	11	6.2
Education level		
Associate degree or below	23	12.9
Bachelor degree	91	51.1
Master degree and above	64	36.0
Education background		
Medicine	53	29.8
Pharmacy	86	48.3
Nursing	20	11.2
Biotechnology	14	7.9
Public health	5	2.8
Company type		
Multinational CRO	74	41.6
Local CRO	59	33.1
Multinational Pharmaceutics	32	18.0
Local Pharmaceutics	13	7.3

Table 1: Demographic Data on Participants (N=178).

Variable	Total (n=178)	Male (n=51)	Female (n=127)	t	P value
Occupational Role Questionnaire [ORQ]	139.30 ± 16.59	142.06 ± 18.85	138.19 ± 15.53	1.411	0.160
Role Overload [RO]	27.81 ± 4.44	28.39 ± 4.27	27.58 ± 4.50	1.100	0.273
Role insufficiency[RI]	25.39 ± 3.95	26.20 ± 3.62	25.07 ± 4.05	1.728	0.086
Role ambiguity [RA]	21.42 ± 4.17	21.51 ± 3.53	21.39 ± 4.41	0.179	0.858
Role boundary [RB]	21.63 ± 4.30	22.02 ± 4.68	21.47 ± 4.15	0.766	0.445
Responsibility [R]	23.42 ± 5.08	24.18 ± 4.63	23.11 ± 5.24	1.268	0.206
Physical environment [PE]	19.62 ± 4.77	19.76 ± 5.84	19.57 ± 4.30	0.219	0.827
Personal Strain Questionnaire [PSQ]	92.25 ± 17.14	95.24 ± 19.61	91.06 ± 15.98	1.476	0.142
Vocational strain [VS]	20.45 ± 4.95	21.73 ± 5.99	19.94 ± 4.39 a	2.203	0.029
Psychological strain [PSY]	24.59 ± 6.04	25.08 ± 6.26	24.39 ± 5.96	0.683	0.496
Interpersonal strain [IS]	24.40 ± 3.94	24.94 ± 4.03	24.19 ± 3.89	1.154	0.250
Physical strain [PHS]	22.81 ± 6.05	23.49 ± 6.23	22.54 ± 5.98	0.952	0.342
Personal Resources Questionnaire [PRQ]	126.33 ± 14.46	124.76 ± 14.34	126.95 ± 14.52	-0.912	0.363
Recreation [RE]	27.89 ± 4.75	27.86 ± 4.30	27.90 ± 4.93	-0.044	0.965
Self-care [SC]	29.62 ± 5.20	28.33 ± 5.11	30.13 ± 5.16 a	-2.110	0.036
Social support [SS]	36.43 ± 5.08	35.86 ± 5.15	36.66 ± 5.06	-0.948	0.345
Rational coping [RC]	32.39 ± 5.25	32.71 ± 5.19	32.26 ± 5.29	0.511	0.610
[a]statistically significant compared with male group.					

Table 2: Occupational Stress of CRAs of Different Gender (Mean ± SD).

Variable	Total (n=178)	≤ 25 years (n=41)	26- years (n=86)	31- years (n=40)	≥ 36 years (n=11)	F	P value
Occupational Role Questionnaire[ORQ]	139.30 ± 16.59	139.63 ± 16.68	138.93 ± 16.99	139.32 ± 15.80	140.82 ± 18.02	0.05	0.985
Role Overload [RO]	27.81 ± 4.44	27.93 ± 4.74	27.93 ± 4.57	27.53 ± 3.96	27.55 ± 4.44	0.10	0.962
Role insufficiency[RI]	25.39 ± 3.95	25.93 ± 3.69	25.41 ± 4.17	25.30 ± 3.42	23.64 ± 4.86	0.98	0.403
Role ambiguity [RA]	21.42 ± 4.17	23.22 ± 3.84	21.26 ± 4.21	20.43 ± 3.58[a]	19.64 ± 5.26[a]	4.24	0.006
Role boundary [RB]	21.63 ± 4.30	21.37 ± 4.49	21.41 ± 4.24	21.98 ± 3.75	23.09 ± 6.01	0.63	0.595
Responsibility [R]	23.42 ± 5.08	21.29 ± 4.74	23.27 ± 4.55	24.60 ± 5.45[a]	28.18 ± 5.12[a, b, c]	7.01	<0.001
Physical environment [PE]	19.62 ± 4.77	19.90 ± 4.72	19.66 ± 4.63	19.50 ± 5.48	18.73 ± 3.74	0.18	0.907
Personal Strain Questionnaire[PSQ]	92.25 ± 17.14	95.90 ± 19.13	91.40 ± 15.54	92.68 ± 16.66	83.82 ± 21.54	1.60	0.191
Vocational strain [VS]	20.45 ± 4.95	21.66 ± 5.96	20.69 ± 4.56	19.55 ± 4.41	17.36 ± 4.34[a, b]	2.83	0.040
Psychological strain [PSY]	24.59 ± 6.04	24.88 ± 5.93	24.15 ± 5.74	25.70 ± 6.56	22.91 ± 6.89	0.92	0.435
Interpersonal strain [IS]	24.40 ± 3.94	25.49 ± 4.05	24.02 ± 3.88	24.43 ± 3.57	23.27 ± 4.86	1.62	0.185
Physical strain [PHS]	22.81 ± 6.05	23.88 ± 5.99	22.53 ± 5.54	23.00 ± 6.67	20.27 ± 7.55	1.15	0.332
Personal Resources Questionnaire[PRQ]	126.33 ± 14.46	120.73 ± 12.54	126.84 ± 13.79	128.85 ± 14.99	134.00 ± 18.97[a]	3.68	0.013
Recreation [RE]	27.89 ± 4.75	26.93 ± 4.55	28.02 ± 4.22	28.43 ± 5.15	28.45 ± 7.45	0.80	0.493
Self-care [SC]	29.62 ± 5.20	26.85 ± 3.92	30.10 ± 4.99[a]	30.33 ± 5.76[a]	33.55 ± 4.80 [a, b, c]	7.13	<0.001
Social support [SS]	36.43 ± 5.08	35.34 ± 4.55	36.74 ± 5.33	37.03 ± 4.32	35.91 ± 7.23	0.96	0.414
Rational coping [RC]	32.39 ± 5.25	31.61 ± 4.81	31.97 ± 4.75	33.08 ± 5.88	36.09 ± 6.93 [a, b, c]	2.61	0.053
[a]statistically significant compared with ≤25 years group. [b]statistically significant compared with 26- years group. [c]statistically significant compared with 31- years group.							

Table 3: Occupational Stress of CRAs of Different Age Groups(Mean ± SD).

The means and standard deviation of the measured variables are presented in Table 3.

The occupational stress in different education levels was assessed. No difference of the work stressor and personal strain subsets and facets were observed among participants with different education levels ($P \geq 0.05$). There was also no difference for coping resources, except responders of master degree and above obtained higher score in the self-care facet score compared with other groups ($P<0.05$). The means and standard deviation of the measured variables are presented in Table 4.

We evaluated the occupational stress from different types of companies. There was no difference of the work stressor or personal strain subsets and facets among participants from different types of company ($P \geq 0.05$).The self-care facet scores of participants from multinational CRO were significantly higher than that of other groups ($P<0.05$). The means and standard deviation of the measured variables are presented in Table 5.

Positive correlation between work stressor subset and personal strain subset as well as their facets were observed, indicated higher work stressor increased strains. Negative correlations were observed

Variable	Total (n=178)	Associate and below (n=23)	Bachelor (n=91)	Master and above (n=64)	F	P value
Occupational Role Questionnaire[ORQ]	139.30 ± 16.59	141.78 ± 12.10	139.63 ± 17.45	137.94 ± 16.82	0.488	0.615
Role Overload [RO]	27.81 ± 4.44	28.35 ± 4.76	27.98 ± 4.48	27.39 ± 4.30	0.517	0.598
Role insufficiency[RI]	25.39 ± 3.95	26.52 ± 4.18	25.46 ± 3.66	24.89 ± 4.22	1.478	0.231
Role ambiguity [RA]	21.42 ± 4.17	22.04 ± 4.20	21.81 ± 4.06	20.64 ± 4.26	1.794	0.169
Role boundary [RB]	21.63 ± 4.30	22.17 ± 4.54	21.44 ± 4.47	21.70 ± 4.02	0.280	0.756
Responsibility [R]	23.42 ± 5.08	23.48 ± 4.70	23.15 ± 5.27	23.77 ± 4.98	0.272	0.762
Physical environment [PE]	19.62 ± 4.77	19.22 ± 5.11	19.78 ± 5.13	19.55 ± 4.15	0.139	0.870
Personal Strain Questionnaire[PSQ]	92.25 ± 17.14	93.22 ± 14.43	93.56 ± 17.66	90.05 ± 17.31	0.829	0.438
Vocational strain [VS]	20.45 ± 4.95	20.83 ± 5.56	20.69 ± 5.03	19.97 ± 4.64	0.475	0.623
Psychological strain [PSY]	24.59 ± 6.04	23.48 ± 5.04	25.21 ± 6.02	24.11 ± 6.37	1.071	0.345
Interpersonal strain [IS]	24.40 ± 3.94	24.83 ± 4.05	24.41 ± 4.04	24.25 ± 3.79	0.180	0.836
Physical strain [PHS]	22.81 ± 6.05	24.09 ± 5.56	23.25 ± 6.15	21.72 ± 5.99	1.814	0.166
Personal Resources Questionnaire[PRQ]	126.33 ± 14.46	122.87 ± 11.55	124.47 ± 13.54	130.20 ± 15.96[a]	3.823	0.024
Recreation [RE]	27.89 ± 4.75	27.83 ± 3.63	27.36 ± 4.85	28.66 ± 4.91	1.403	0.249
Self-care [SC]	29.62 ± 5.20	28.26 ± 4.65	28.81 ± 4.90	31.25 ± 5.45[a, b]	5.272	0.006
Social support [SS]	36.43 ± 5.08	35.48 ± 5.61	36.24 ± 4.63	37.05 ± 5.49	0.936	0.394
Rational coping [RC]	32.39 ± 5.25	31.30 ± 4.23	32.05 ± 5.00	33.25 ± 5.85	1.544	0.216

[a]statistically significant compared with Associate and below group.
[b]statistically significant compared with Bachelor group.

Table 4: Occupational Stress of CRAs with Different Education Levels(Mean ± SD).

Variable	Total (n=178)	Local Pharmaceuticals (n=13)	Local CRO (n=59)	Multinational Pharmaceuticals (n=32)	Multinational CRO (n=74)	t	P value
Occupational Role Questionnaire [ORQ]	139.30 ± 16.59	139.62 ± 16.23	141.69 ± 18.25	144.72 ± 15.15	134.99 ± 15.01	0.488	0.615
Role Overload [RO]	27.81 ± 4.44	27.62 ± 3.64	29.00 ± 4.92	28.13 ± 4.98	26.77 ± 3.68	0.517	0.598
Role insufficiency[RI]	25.39 ± 3.95	26.38 ± 4.41	25.68 ± 4.37	25.69 ± 3.62	24.86 ± 3.65	1.478	0.231
Role ambiguity [RA]	21.42 ± 4.17	22.38 ± 3.75	21.95 ± 4.43	22.09 ± 3.70	20.54 ± 4.13	1.794	0.169
Role boundary [RB]	21.63 ± 4.30	20.85 ± 5.65	21.34 ± 4.12	23.50 ± 3.88	21.19 ± 4.23	0.280	0.756
Responsibility [R]	23.42 ± 5.08	23.31 ± 5.68	23.86 ± 5.77	24.22 ± 5.20	22.73 ± 4.29	0.272	0.762
Physical environment [PE]	19.62 ± 4.77	19.08 ± 6.69	19.86 ± 4.56	21.09 ± 4.73	18.89 ± 4.50	0.139	0.870
Personal Strain Questionnaire [PSQ]	92.25 ± 17.14	89.08 ± 13.23	93.80 ± 19.85	93.75 ± 16.28	90.93 ± 15.87	0.829	0.438
Vocational strain [VS]	20.45 ± 4.95	19.31 ± 3.79	20.95 ± 5.95	20.28 ± 5.42	20.32 ± 4.00	0.475	0.623
Psychological strain [PSY]	24.59 ± 6.04	23.38 ± 3.82	25.47 ± 6.32	24.97 ± 6.22	23.93 ± 6.04	1.071	0.345
Interpersonal strain [IS]	24.40 ± 3.94	24.23 ± 3.63	23.93 ± 4.35	24.34 ± 3.62	24.84 ± 3.80	0.180	0.836
Physical strain [PHS]	22.81 ± 6.05	22.15 ± 5.74	23.44 ± 6.76	24.16 ± 5.50	21.84 ± 5.66	1.814	0.166
Personal Resources Questionnaire [PRQ]	126.33 ± 14.46	118.77 ± 17.49	123.53 ± 13.76	126.28 ± 14.55	129.91 ± 13.68[a]	3.823	0.024
Recreation [RE]	27.89 ± 4.75	26.31 ± 5.39	26.22 ± 4.52	28.03 ± 4.58	29.43 ± 4.43[a, b]	1.403	0.249
Self-care [SC]	29.62 ± 5.20	27.15 ± 3.58	28.39 ± 5.38	29.59 ± 5.39	31.04 ± 4.87[a]	5.272	0.006
Social support [SS]	36.43 ± 5.08	33.23 ± 6.95	36.85 ± 5.11[a]	36.28 ± 3.85[a]	36.73 ± 5.06[a]	0.936	0.394
Rational coping [RC]	32.39 ± 5.25	32.08 ± 6.92	32.07 ± 5.02	32.38 ± 5.84	32.70 ± 4.93	1.544	0.216

[a] statistically significant compared with Local Pharmaceuticals group.
[b] statistically significant compared with local CRO group.

Table 5: Occupational Stress of CRAs from Different Type of Companies (Mean ± SD).

between coping resources subsets and personal strain subsets as well as their facets; implied stronger coping resources decreased strains. A correlation matrix for the variables is presented in Table 6. The regression equations are listed below:

$$y1=11.495+0.591x1+0.181x2-0.114x5-0.203x7$$

$$y2=18.442+0.348x1+0.315x2+0.207x3-0.486x5$$

$$y3=22.271+0.330x2-0.137x6$$

$$y4=29.498+0.365x2+0.275x3-0.307x4-0.385x5$$

Whereas y1 is Vocation Strain, y2 is Psychological Strain, y3 is Interpersonal Strain, y4 is Physical Strain; x1 is Role Insufficiency, x2 is Role Boundary, x3 is Physical Environment, x4 is Recreation, x5 is Self-care, x6 is Social Support, x7 is Rational Coping.

The Beta weight suggested the relative importance of the facets in predicting the strain variables. It was demonstrated that Role Insufficiency and Role Boundary were of great consequence on increased strain, while Rational Coping, Recreation, Social Support and Self-care resources all contributed to decrease strain.

The T score of work stressor and personal strain subsets and all their relevant facets were within the range of $40 \leq T \leq 59$, indicated the CRAs had moderate work stressor and personal strain. The criteria of

stress norm developed by Yang [22] are presented in Table 7 [24]. The means and standard deviation of the measured variables and T score are presented in Table 8 and 9. The T score of coping resources subset and all its relevant facets were within the range of 40 ≤ T≤ 59, implied moderate coping resources. The means and standard deviation of the measured variables and T score are presented in Table 10.

Model	B	SE	Beta	t	P value
Vocational strain [VS]					
Constant	11.495	3.609		3.185	.002
Role insufficiency[RI]	.591	.077	.472	7.702	<0.001
Rational coping [RC]	-.203	.057	-.216	-3.558	<0.001
Role boundary [RB]	.181	.065	.158	2.793	.006
Self-care [SC]	-.114	.054	-.120	-2.096	.038
Psychological Strain [PSY]					
Constant	18.442	3.793		4.863	<0.001
Recreation [RE]	-.486	.078	-.382	-6.264	<0.001
Role boundary [RB]	.315	.094	.224	3.359	.001
Role insufficiency[RI]	.348	.099	.228	3.509	.001
Physical environment [PE]	.207	.080	.163	2.593	.010
Interpersonal Strain [IS]					
Constant	22.271	2.679		8.313	<0.001
Role boundary [RB]	.330	.064	.361	5.156	<0.001
Social support [SS]	-.137	.054	-.177	-2.533	.012
Physical Strain [PHS]					
Constant	29.498	3.306		8.921	<0.001
Self-care [SC]	-.385	.074	-.331	-5.173	<0.001
Role boundary [RB]	.365	.085	.260	4.292	<0.001
Recreation [RE]	-.307	.080	-.241	-3.827	<0.001
Physical environment [PE]	.275	.077	.217	3.574	<0.001

Table 6: Correlation Matrix between Work Stressor, Coping Resources and Personal Strain.

T Score	Occupational Role Questionnaire	Personal Strain Questionnaire [PSQ]	Personal Resources Questionnaire [PRQ]
≥70	High stressor	High strain	-
60 ≤T≤ 69	Middle stressor	Middle strain	-
40 ≤T≤ 59	Moderate stressor	Moderate strain	-
T <40	Lack of stressor	Lack of strain	-
≥60	-	-	Strong coping resources
40 ≤T≤ 59	-	-	Moderate coping resources
30≤T≤39	-	-	Middle lack of coping resources
T <30	-	-	Lack of coping resources

Table 7: Criteria Of Stress Norm Classification.

Conclusion and Discussion

Clinical trial is considered a breakthrough method in medicine and essential to the development of new drugs. The monitor's work have great consequence of the quality of clinical trials. Our study revealed the occupational stresses were varying amongst Chinese CRAs of different gender, ages, education levels and company types.

We noticed the work stressor was pertaining to age and there were no difference with regard to gender, education levels, or company types. Specifically, age was a factor affecting Role Ambiguity and Responsibility. In CRAs of age ≤ 25 years, Role Ambiguity was higher than 31- and ≥ 36 age groups, with a pattern of diminished role ambiguity toward higher ages. This was reasonable that younger fresh CRAs usually have little experience and need more detailed instructions. Responsibility was higher in CRAs of age ≥36 years than any of the other age groups, with a trend of lower responsibility toward lower ages. The finding might imply that managers tend to assign more responsibilities to elder CRAs. It suggested that precaution should be taken to assess the stress status of an elder CRA before allocate extra work.

The personal strain, especially vocational strain was shown to be related to gender and age, and no difference was observed among CRAs with different education levels or company types. Vocational Strain (VS) was higher in male participants than females, and was highest in the participants of age ≤ 25 among all age groups with a trend of higher strain toward younger ages.

As for coping resources, we observed that self-care varied amongst CRAs of different gender, ages, education levels, or company types. Higher self-care resources were seen in females, elder age groups, those of higher education levels and in multinational CROs. Rational coping was higher in ≥ 36 year of age groups than any of the other groups with a trend of lower resources toward younger ages. Both Recreation and Social Support were highest in multinational CROs, while local pharmaceuticals seemed to have lowest personal resources. This was consistent with our experience that global CROs and pharmaceuticals usually had systematic support and more chance of entertainments [25].

The above results were obtained directly from the hypothesis to test a difference significant at 1/20 in theory. We noticed it was precautious

Variable	Occupational Role Questionnaire [ORQ]	Role Overload[RO]	Role Insufficiency [RI]	Role Ambiguity [RA]	Role Boundary [RB]	Responsibility [R]	Physical Environment[PE]
Raw score	139.30 ± 16.59	27.81 ± 4.44	25.39 ± 3.95	21.42 ± 4.17	21.63 ± 4.30	23.42 ± 5.08	19.62 ± 4.77
T score	50.00 ± 10.00	50.01 ± 10.00	50.00 ± 10.00	50.00 ± 10.00	50.00 ± 10.01	49.99 ± 10.00	50.01 ± 10.01

Table 8: Work Stressor T Scores of CRAs.

Variable	Personal Strain Questionnaire [PSQ]	Vocational strain [VS]	Psychological Strain [PSY]	Interpersonal Strain [IS]	Physical Strain [PHS]
Raw score	92.25 ± 17.14	20.45 ± 4.95	24.59 ± 6.04	24.40 ± 3.94	22.81 ± 6.05
T score	50.00 ± 10.00	50.00 ± 10.00	50.00 ± 10.00	50.01 ± 9.99	50.00 ± 10.00

Table 9: Personal Strain T Scores of CRAs.

Variable	Personal Resources Questionnaire [PRQ]	Recreation [RE]	Self-care [SC]	Social Support [SS]	Rational/Cognitive [RC]
Raw score	126.33 ± 14.46	27.89±4.75	29.62 ± 5.20	36.43 ± 5.08	32.39 ± 5.25
T score	50.00 ± 10.00	50.00 ± 10.00	50.00 ± 10.00	50.01 ± 10.00	50.00 ± 10.00

Table 10: Coping Resources T Scores of CRAs.

to consider Bonferroni correction when conducted numerous independent statistical tests on the same dataset. It revealed that only role ambiguity of age of ≤ 25, responsibility of age of ≥ 36, self-care of age of ≥ 36 and of master and above education level remained statically significant when Bonferroni correction were applied. The missing of statistical significance of some variables after Bonferroni correction might be a consequence of relatively smaller sample size in our study.

Our further correlation analysis revealed role insufficiency and Role Boundary were the main risk factors of strain, while Rational Coping, Recreation, Social Support and Self-care were the protecting factors. Insufficient training might be one of the underlying causes to Role Insufficiency. Since the Chinese clinical research industry had a history only less than fifteen years, the CRA training system was under the way to establish. In general, the existing CRA supply pipelines were, graduates with medicine or pharmacy background with several days or weeks of training. Majority of the companies didn't have the capability to provide systematic training to the CRAs, that self-read of the SOPs were often the only way to prepare a CRA. We suggested robust training would be an effective method to better prepare CRA and reduce role insufficiency. Role boundary was considered to have some relationship with bearing invisible work or responsibilities. In Chinese hospitals, it was a common issue that there was lack of specific resources for clinical trials [26]. Clinical doctors and nurses took up clinical trial responsibilities on top of their daily routine medical practice. It was usually the case that Chinese CRAs repeatedly reminded investigators to complete source documents. In the mean time, the doctors or nurses, due to full occupied in daytime, worked late to complete records and reports but at poor quality, which in turn increased burden for monitoring. It suggested clearly defined role in connection with CRAs internally and externally might help to reduce the strain of CRAs. Additionally as shown from the correlation analysis between coping resources and personal strain, every type of personal resource would be an effective means to cope with strain and energise CRAs.

Based on the Bonferroni correction, a more careful conclusion could be drawn that the CRAs of age ≤ 25 years had higher vocational strain than other age groups, while male and female CRAs were of similar strain. It was noticeable that the CRAs at age of ≤ 25 years represented around one fourth participants in this study. Based our experience and view of peers from Europe and US, the proportion was much lower in western countries where fresh graduates started from Research Associate (RA) in the first several years. It might be due to fast industry expansion and huge resource demand in China that younger graduates were quickly absorbed into the role. The study suggested additional supports specifically to this ≤ 25 years CRA group might be necessary.

We also drew a preliminary conclusion, based on an occupational stress standard norm in Chinese employment, that the Chinese CRAs had moderate work stressor, personal strain and coping resources. It would be more rigorous to address the question by comparing with a well-defined population of similarity. However we could not find any published research on the CRAs occupation stress internationally, also a parallel comparison with counterpart from other countries was unfeasible due to the limitation.

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