The psychometric properties of the workplace resilience for clinical research nurses in Taiwan

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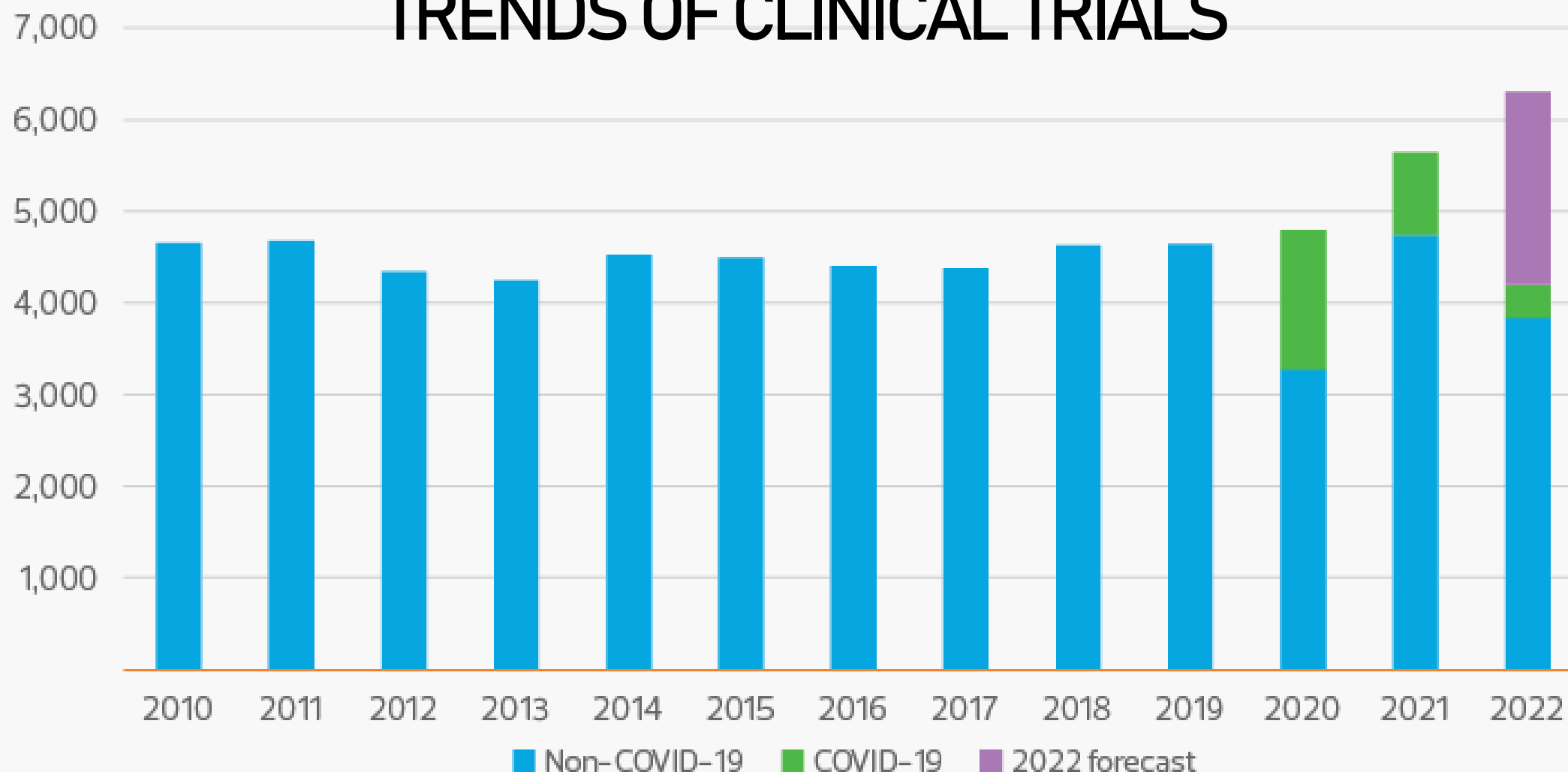University Hospital

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TRENDS OF CLINICAL TRIALS

Source: ClinicalTrials.gov; RSM US LLP

*count; industry-funded; interventional

https://rsmus.com/insights/industries/life-sciences/clinical-trials-trends.html

🌐 **72%** of the approved clinical trials in Taiwan are MRCTs.

Table1 . Approved IND Cases in Taiwan by Year, 2010–2020

Left axis (case): 0, 50, 100, 150, 200, 250, 300, 350, 400
Right axis (%): 0, 10, 20, 30, 40, 50, 60, 70, 80, 90

MRCT values by year: 67, 64, 78, 69, 69, 74, 77, 72, 73, 81, 72

Years: 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020

Legend: ■ Phase I ■ Phase II ■ Phase III ■ Phase IV / Others ─○─ MRCT
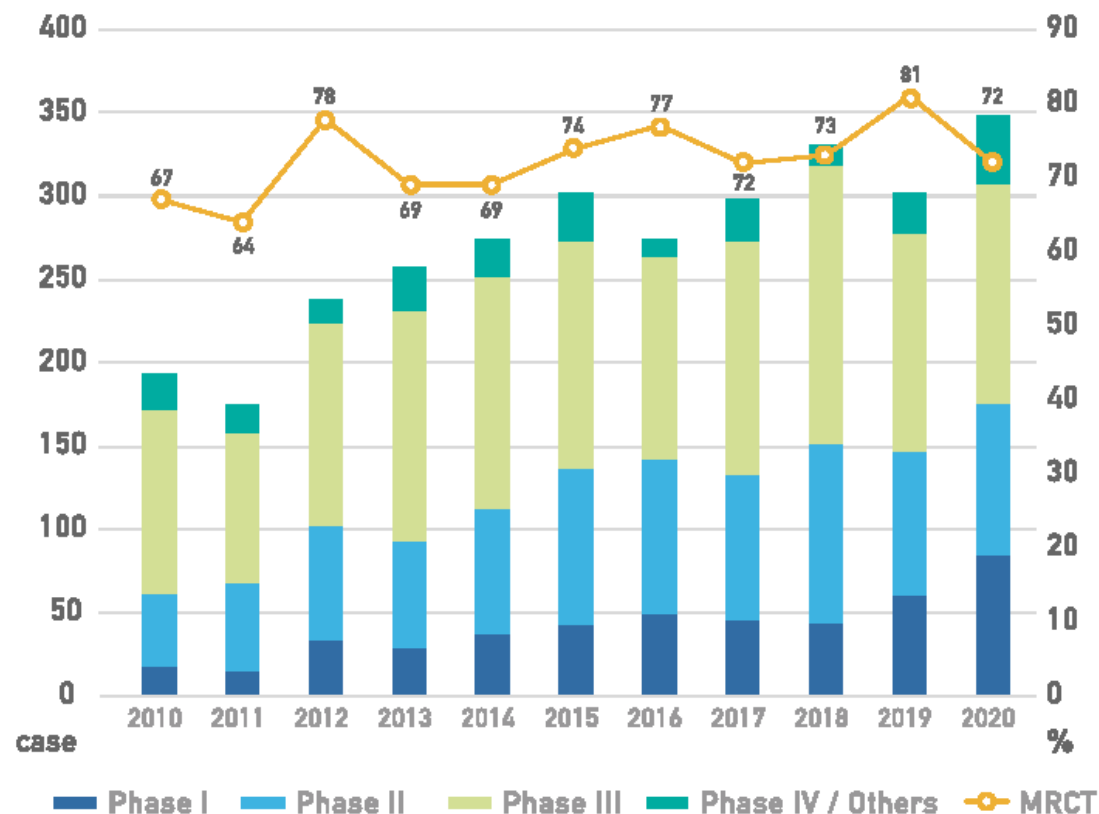
Table2 . The Percentage of IND Approval by Therapeutic Area, 2016–2020

Pie chart values:
- Oncology — 40
- Infectious Disease — 8
- Musculoskeletal Disease — 5
- Endocrine, Nutritional and Metabolic Diseases, and Immunity Disorders — 5
- Dermatology — 6
- Neurology — 6
- Respiratory Disease — 3
- Gastroenterology — 4
- Cardiovascular Disease — 4
- Other — 19

UNIT : %
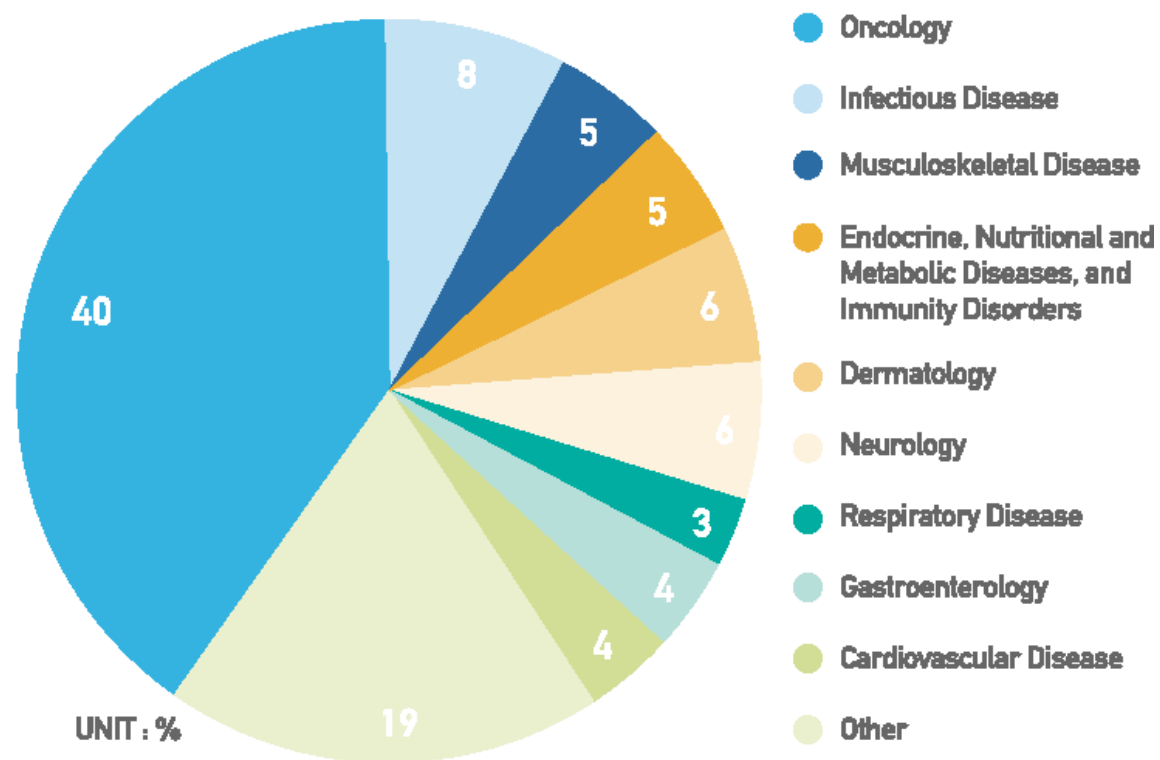
EXPEDITED REVIEW PROCESS

Clinical Trial Notification

15 Days *Average review time: 11.2 days (2020)*

Regenerative Medicine IND

https://www.taiwanclinicaltrials.tw/

22 MEDICAL CENTER HOSPITALS IN TAIWAN

Clinical Trial Center National Cheng-Kung University Hospital
1,343 beds
801 doctors

National Taiwan University Hospital Clinical Trial Center
2,600 beds
1,008 doctors

Joint Clinical Research Center, Taipei Medical University
2,648 beds
834 doctors

北醫大醫療體系
Taipei Medical University
Taipei Medical University Hospital
Wan Fang Hospital
Shuang Ho Hospital

Chang Gung Memorial Hospital, Linkou, Clinical Trial Center
10,058 beds
1,827 doctors

China Medical University Hospital Clinical Trial Center
2,076 beds
884 doctors

KMUH Clinical Trial Center
1,704 beds
806 doctors

Taipei Veterans General Hospital General Clinical Research Center
2,802 beds
1,416 doctors

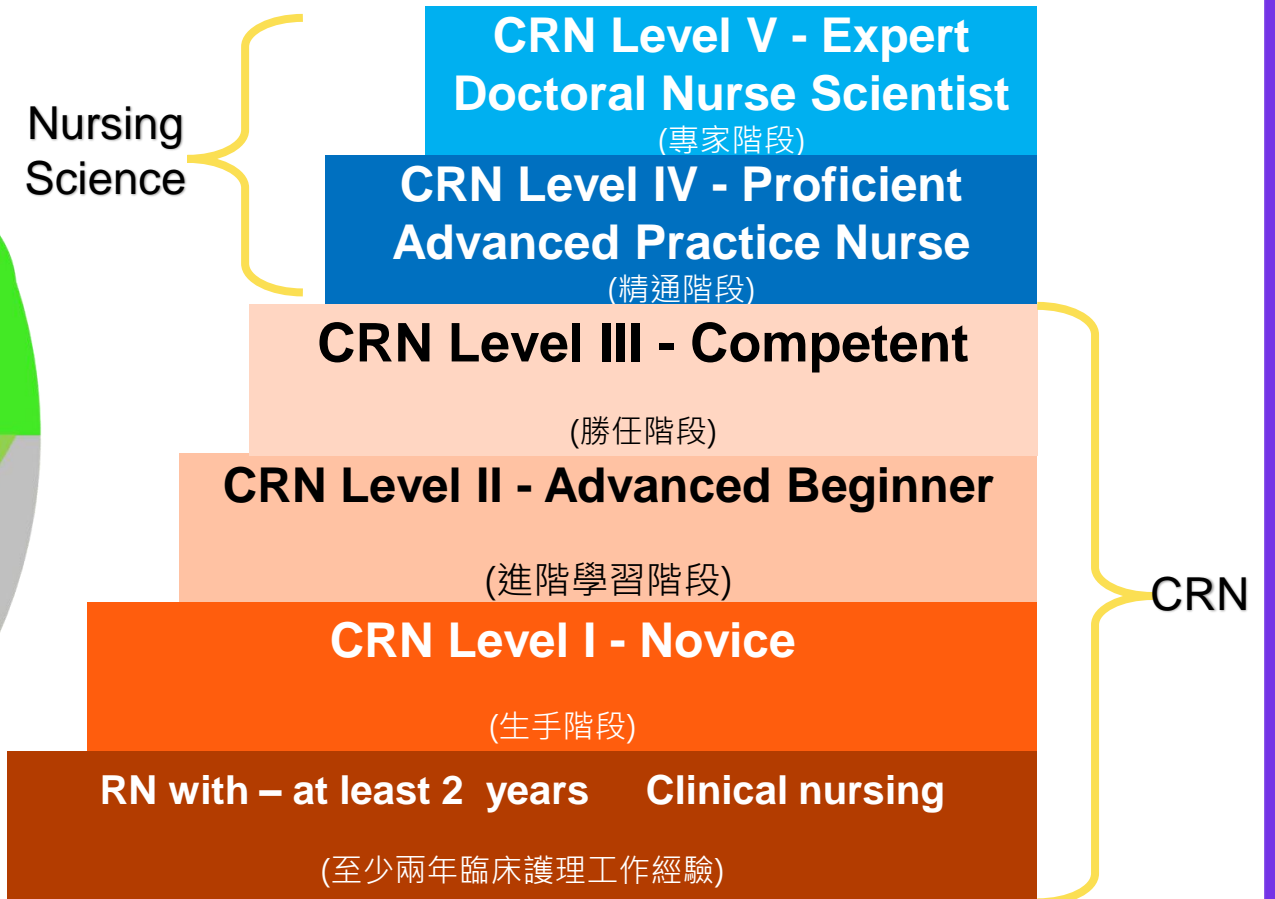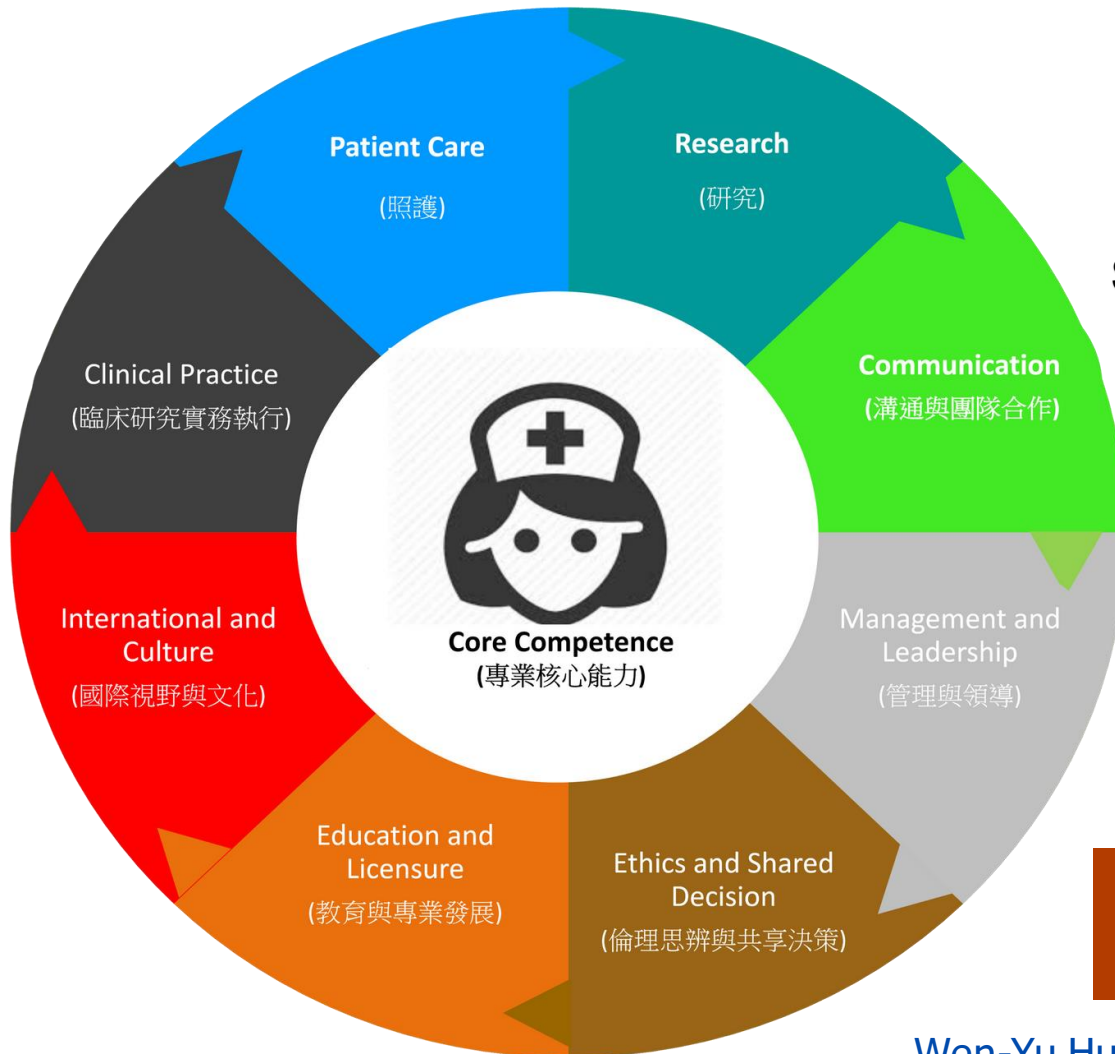**Cathay General Hospital Center of Clinical Trial and Research**
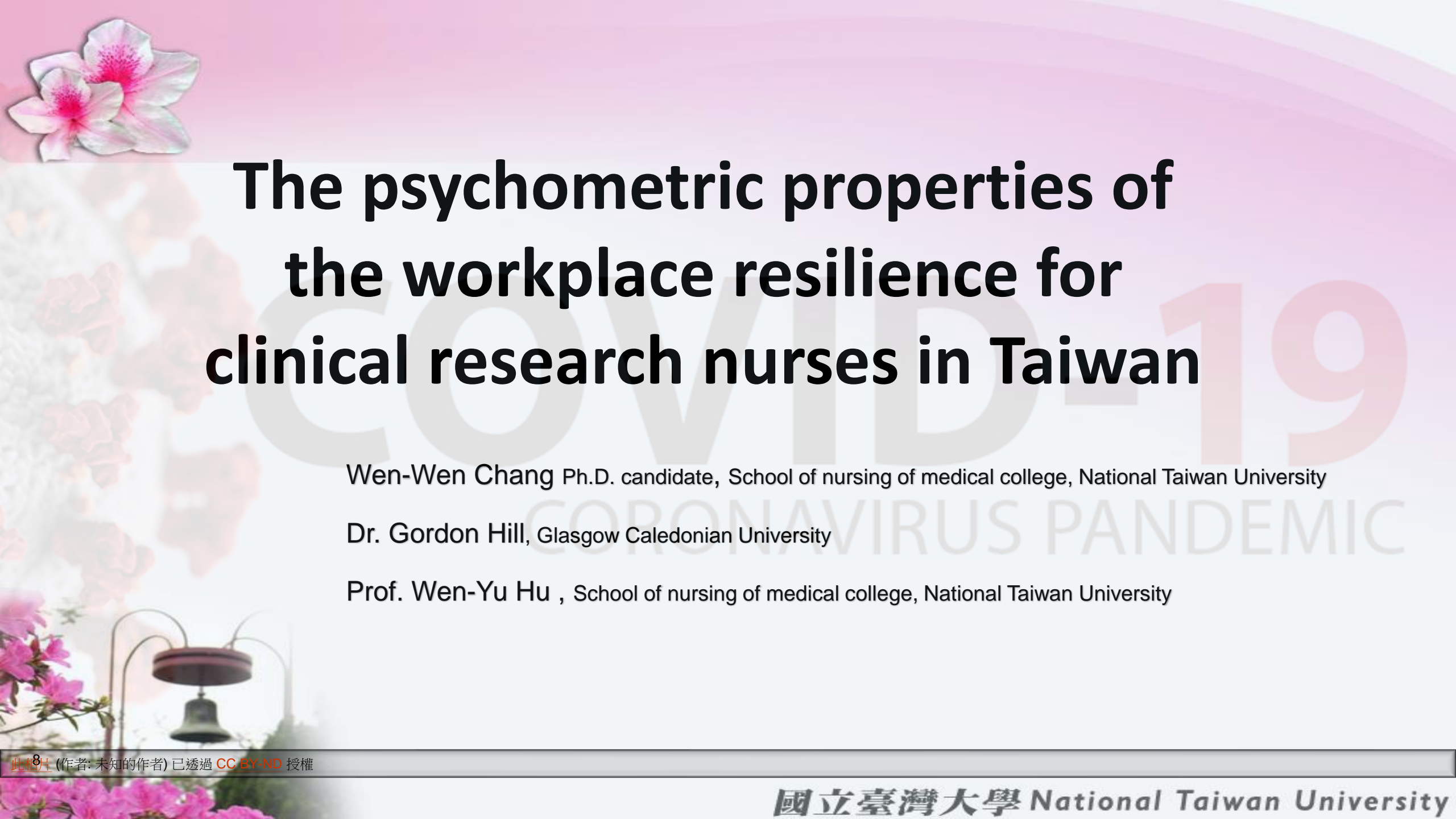839 beds
365 doctors

Chi Mei Hospital Clinical Trial Center
1,288 beds
677 doctors

WHAT ARE THE 「CORE COMPETENCIES」 OF CLIINIICAL RESEARCH NURSE ?

Wen-Yu Hu, Shih-Ping Wang, Guey-Shiun Huang 2019 IACRN poster

The psychometric properties of the workplace resilience for clinical research nurses in Taiwan

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Background

- The escalation of community-transmitted infection of the Coronavirus (COVID-19) pandemic occurred in 2021 impacted on a number of areas of clinical research nurses' (CRNs) work.

- Building CRNs' workplace resilience to complex and stressful practice environments is necessary to ensuring **research quality** and **safe patient care**.

Aims

Developing the psychometric properties on the resilience at work of clinical research nurses.

Designs

- **on-line questionnaire survey**

- cross-sectional design.

- Participants in Taiwan were recruited **from Aug to Nov 2021** by using purposive and snowball sampling.

workplace resilience

Construct 1

Construct 2

Item 1

Item 2

Item 3

1
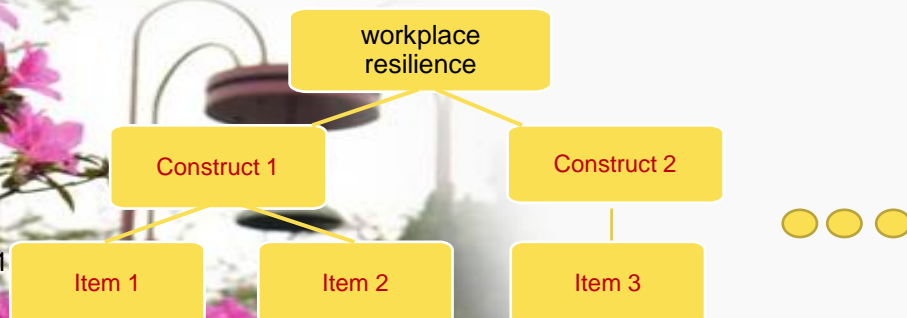
Definition of personal resilience at work

➢ Resilience is an ability that staff in organizations needed to over come and cope with daily stress of tasks as well as to adapt to large-scale organizational change (Warner & April, 2012).

➢ Phenomenon: a common adaptive human process (Rees et al, 2015; Richardson, 2002)

- Identification of traits of resilience.
- Processes of development and operation of resilience, and
- Incorporating the life force to heal, recover and even emerge strengthened.

➢ Results of Resilience:

– 'bounce back' after experiencing stressful events, such as significant change, stress, adversity and hardship (Maddi and Khoshaba, 2005).

– Be successful to achieve the task-focus of the organization or mission (with professionalism, competent, well-being)(Chiou, 2006).

– Most importantly, it incorporates the concept of emerging from the adversity stronger and more resourceful (Richardson, 2002).

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What might resilience at work relate to?

Internal

Personal Traits or characters

- ☐ *Think positively*
- ☐ *See challenges*
- ☐ *Awareness*
- ☐ *Boundaries*
- ☐ *Confidence*
- ☐ *Commit to Goals*
- ☐ *Focus on what they can control*
- ☐ *Problem-Solving*
- ☐ *Purpose*
- ☐ *Support*
- ☐

External

Resilience at work*(tough times)*

- ☐ *Ability to remain task-focused*
- ☐ *Achieve productive goals (overcome)*
- ☐ *Connected to the organizational mission*

(Huang, 2013; Lee et al., 2019)

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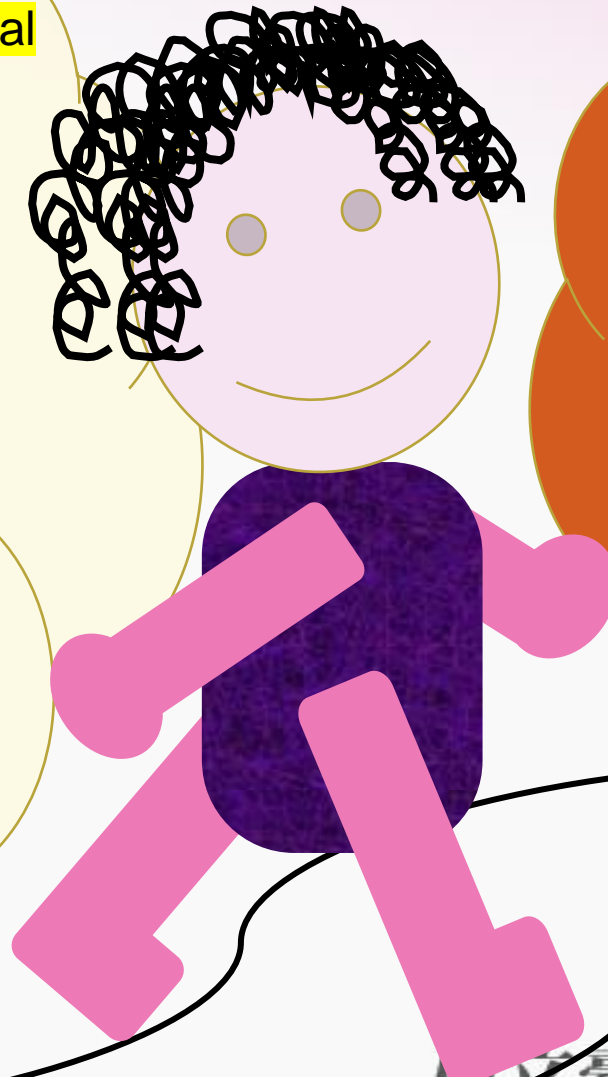
Study Design and Participants

➢ Cross-sectional online survey in Taiwan

➢ Data collection: August to November, 2021

➢ The participants were employed as a clinical research nurse

➢ Measurements and Variables:

– demographic information

• sex; date of birth; education level; marital status; number of children; tenure in clinical research (years or months); job title; highest clinical nursing level obtained; CRN certification; CRN Level 1 certificate)

– impact on work scale

– professional self-efficacy

– workplace resilience scales

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Workplace Resilience Questionnaire Development

➢ Self- developed 30 questions for the concept of previous CRN literatures on roles, job descriptions, tasks, and education.

(Huang, 2013; Kao et al., 2015; Lee et al., 2019)

➢ A 5-point Likert scale was employed, with results ranging from strongly disagree (1 point) to strongly agree (5 points), with higher values representing greater workplace resilience.

➢ The quality of a research instrument is a crucial element that influences the reliability of study results.

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Psychometric Properties Analysis

(Chiou, 2006 ; Lee et al., 2011)

Item Analysis	Exploratory factor analysis(EFA)	Testing the validity and reliability

Item Analysis

(N=56)

Percentiles	Score	n
27	3.11	15
73	3.97	12
		IBM® **SPSS** v22

Exploratory factor analysis(EFA)

KMO and Bartlett's Test for Sampling Adequacy is good
- Principal Component
- Decided total variance explained--Scree Plot
- Rotation:
  1. Varimax
  2. Promax
  3. **Oblimin**

Testing the validity and reliability
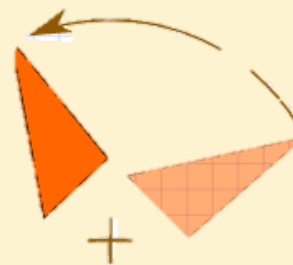
✓ Validity: Content >0.4 & construct validity – Factor analysis

✓ Reliability: Cronbach's α ≧0.7<0.9 indicated its high quality of internal consistency
(Nunnally & Bernstein,1994)

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Demographic data

N=56

		n	%	Mean	S. D
Age					8.79
Tenure					5.837
Tenure gr					
Marriag					
Educ					
Do you hav					
Work S					
Have you had C certifications ?	No	38	67.9		
	Yes	18	32.1		

Resilience total score difference groups

- Low(<=93): 26.8
- Moderate (93-119): 44.6
- High(<119): 28.6

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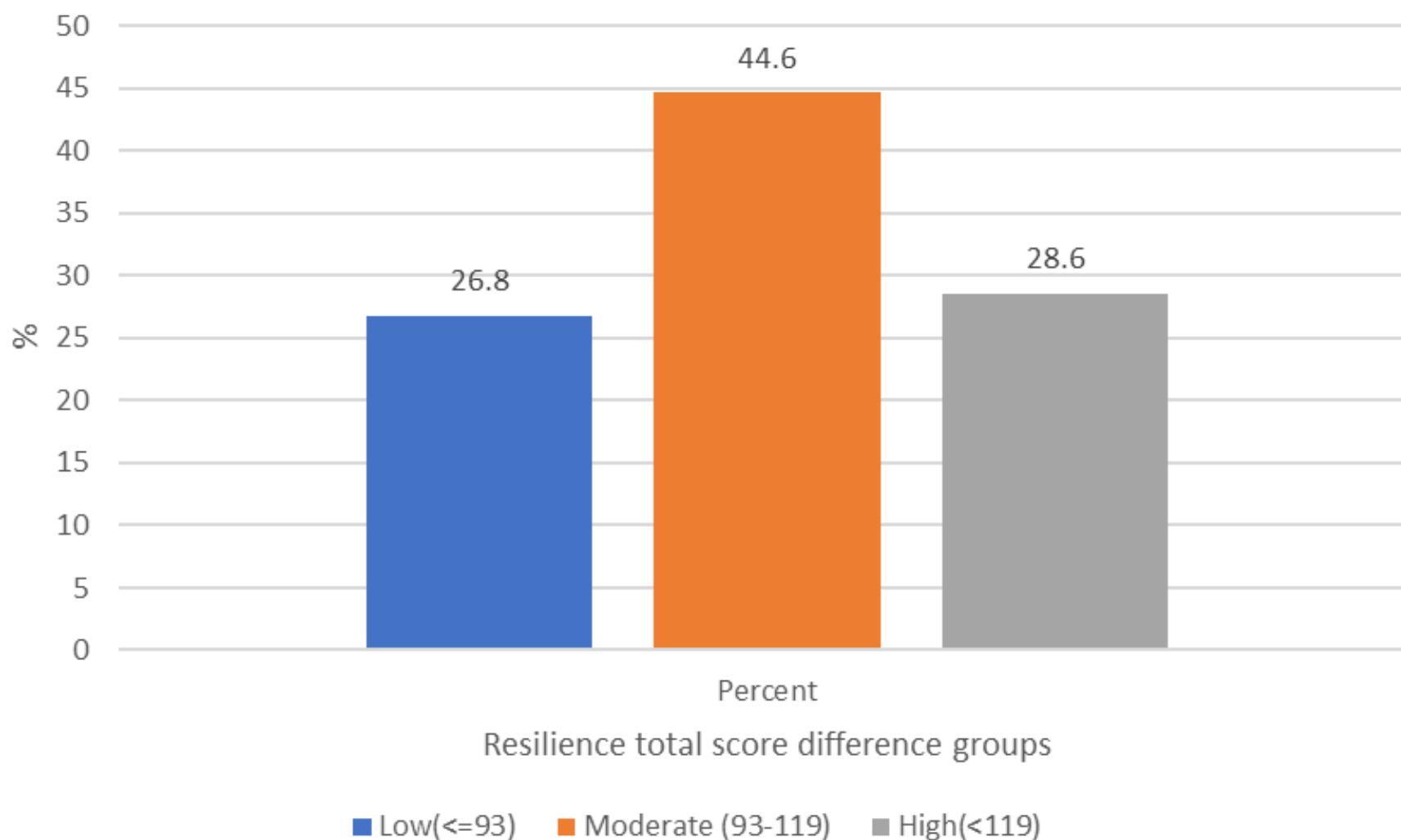
Items	F (Levene's Test for Equality of Variances)	t (t-test for Equality of Means)	P Sig. (2-tailed)
1. I can still quickly restore in the face of setbacks at work.	0.263	-7.014	0.000
2.I can soon understand how to react to clinical trial tasks under all kinds of restrictions of the COVID-19 pandemic	2.090	-8.985	0.000
3.I believe I can overcome the buttle neck of the work.	0.000	-8.784	0.000
4. I remained the same expectation of the clinical trial job even in the situation when it is still in the pandemic	0.171	-4.277	0.000
5. I will try hard to solve job problems in all kinds means.	0.014	-5.063	0.000
6.I will try hard to communicate when other team members have opinions different from mine.	0.664	-4.611	0.000
7.I am willing to take on any challenging job duties.			
8. I can immediately respond and deal with the situation related to anything that happened to the participant			
19. I will not feel myself wrongly or force others when there are unpleasant happen in the workplace.			
20.I will do proper exercise and have mindfulness for releasing the work stress			
21. I will quickly regain my emotional calm when I am accused by my superior.	0.282	-4.109	0.000
22. As a result of the deterioration of the subject's condition, it does not interfere with my normal pace of life.	4.320	-6.524	0.000
23.I will soon come back to work again when any unexpected happens during the trials.	0.705	-6.125	0.000
24.I will always clearly know what to do next though my organization facing a lot of trials and crises at the moment.	1.296	-5.159	0.000
25. I will still actively strive for the opportunity to be vaccinated under the many restrictions.	0.574	-4.378	0.000
26.I will always start a day in a pleasant mood.	0.567	-5.751	0.000
27.I will stay calm when team members unreasonably criticize towards me.	0.567	-5.751	0.000
28.I have the ability to manage trial tasks in order and well organize them step by step.	0.336	-7.716	0.000
29. Even if I encounter troubles at work, I will still maintain an open-minded mood.	0.630	-5.026	0.000
30.II can always take control of the troublesome condition caused by the new-comer of clinical research nurses	0.268	-6.556	0.000

the absolute value of the t value is greater than 3, indicating good discrimination

(N=56)

Group Mean Score	n	Mean (S.D)	F	t (P)
			2.184	-9.356(<0.001)
Low <=3.5	29	3.00(0.457)		
High >3.5	27	3.96(0.286)		

FA Analysis- EFA

Scree Plot

Components: Extract 3 out of 4
Initial Eigenvalues>1
Total Variance Explained: 71.89%
KMO and Bartlett 's Test is good fit
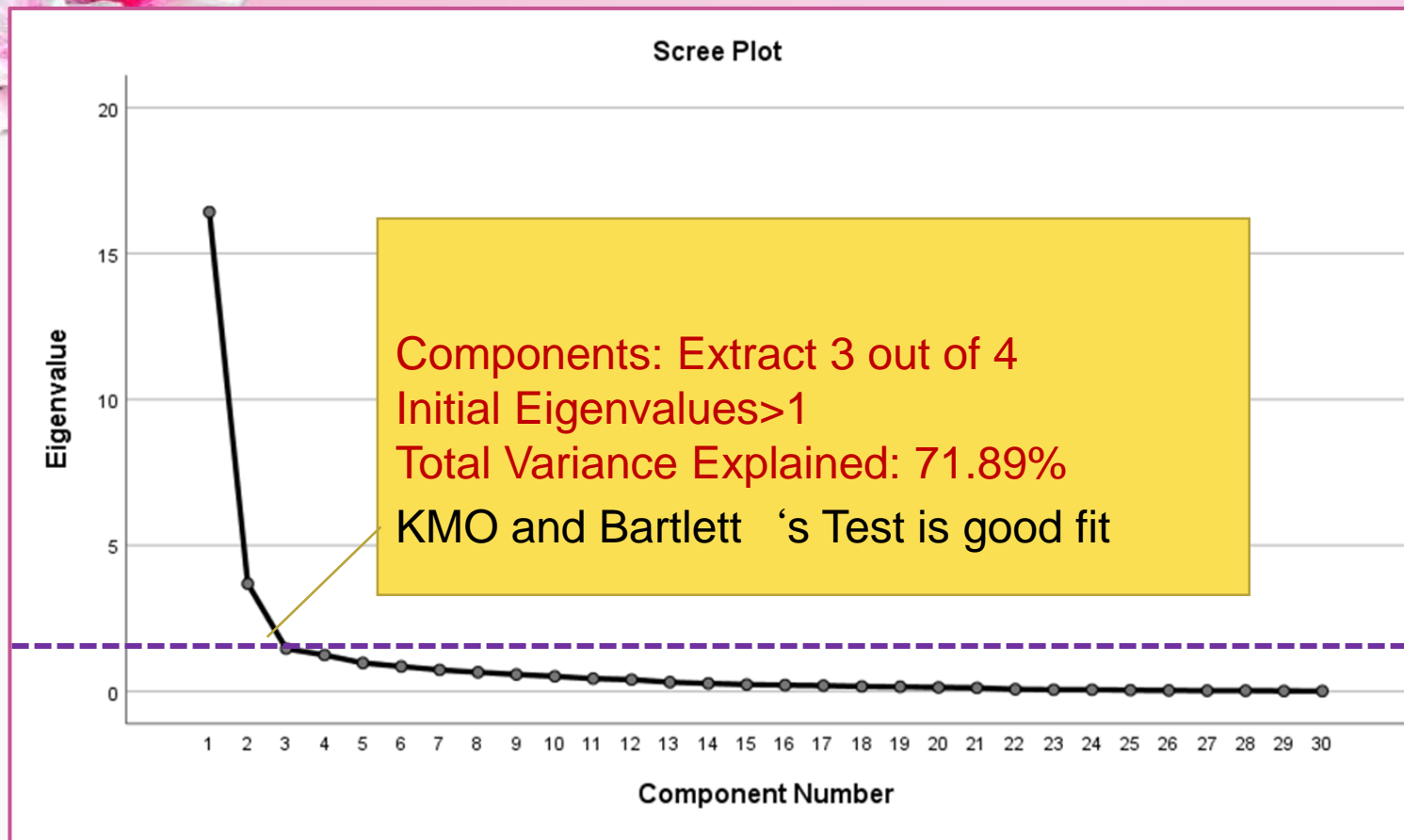
	Total Variance Explained						
Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings[a]
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total
1	16.423	54.742	54.742	16.423	54.742	54.742	13.708
2	3.685	12.283	67.025	3.685	12.283	67.025	10.698
3	1.460	4.865	71.890	1.460	4.865	71.890	7.305
4	1.240	4.132	76.022				
5	0.970	3.233	79.255				
6	0.849	2.831	82.086				
7	0.734	2.446	84.532				
8	0.649	2.164	86.695				
9	0.575	1.918	88.613				
10	0.510	1.701	90.314				
11	0.433	1.443	91.757				
12	0.398	1.325	93.082				
13	0.311	1.037	94.119				
14	0.267	0.889	95.008				
15	0.231	0.769	95.777				
16	0.211	0.703	96.481				
17	0.194	0.648	97.128				
18	0.166	0.553	97.681				
19	0.154	0.512	98.193				
20	0.131	0.436	98.630				
21	0.118	0.392	99.022				
22	0.069	0.231	99.253				
23	0.053	0.177	99.430				
24	0.052	0.173	99.603				
25	0.039	0.130	99.732				
26	0.026	0.087	99.820				
27	0.020	0.068	99.888				
28	0.019	0.065	99.952				
29	0.009	0.029	99.982				
30	0.005	0.018	100.000				

Extraction Method: Principal Component Analysis.

a. When components are correlated, sums of squared loadings cannot be added to obtain a total variance.

Principal components

Promax

Varimax

Oblimin

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Factor loading matrix

Items	1 Professional confidence	2 Positive mindset at work	3 self-perception positively
10.I will aggressively look for resources when I face unfamiliar job tasks.	0.929	0.387	0.219
8. I can immediately respond and deal with the situation related to anything that happened to the participants.	0.921	0.375	0.330
7.I am willing to take on any challenging job duties.	0.920	0.433	0.293
5. I will try hard to solve job problems in all kinds means.	0.898	0.386	0.139
6.I will try hard to communicate when other team members have opinions different from mine.	0.881	0.399	0.274
17.I will aggressively communicate with another department for the job necessarily.	0.873	0.399	0.460
9. I will take it as a personal growth opportunity in the situation of the difficulties in the job.	0.868	0.285	0.401
24.I will always clearly know what to do next though my organization facing a lot of trials and crises at the moment.	0.845	0.348	0.481
28.I have the ability to manage trial tasks in order and well organize them step by step.	0.798	0.517	0.709
4. I remained the same expectation of the clinical trial job even in the situation when it is still in the pandemic	0.745	0.261	0.311
23.I will soon come back to work again when any unexpected happens during the trials.	0.720	0.561	0.625
2.I can soon understand how to react to clinical trial tasks under all kinds of restrictions of the COVID-19 pandemic	0.717	0.708	0.381
30.II can always take control of the troublesome condition caused by the new-comer of clinical research nurses	0.712	0.547	0.455
14. I don't feel overwhelmed when the subject encounters any emergencies.	0.678	0.604	0.485
16.I do not feel any workforce stress when I explain the informed consent to the participants.	0.627	0.401	0.511
11. I will not out of breath though there are work pressure	0.408	0.867	0.226
13. I don't feel pressured for the job assigned by the boss.	0.331	0.862	0.409
12.I don't feel bothered while there are some conflicts between study team members	0.307	0.826	0.176
21. I will quickly regain my emotional calm when I am accused by my superior.	0.334	0.817	0.307
1. I can still quickly restore in the face of setbacks at work.	0.617	0.816	0.370
18.I will not be stressed out even if there is a trial auditor event.	0.414	0.789	0.550
3.I believe I can overcome the buttle neck of the work.	0.668	0.765	0.452
27.I will stay calm when team members unreasonably criticize towards me.	0.428	0.689	0.679
20.I will do proper exercise and have mindfulness for releasing the work stress	0.569	0.635	0.463
22. As a result of the deterioration of the subject's condition, it does not interfere with my normal pace of life.	0.320	0.722	0.610
26.I will always start a day in a pleasant mood.	0.730	0.535	0.597
15. I don't want to quit my CRN job even though the job is stressful.	0.479	0.495	0.740
19. I will not feel myself wrongly or force others when there are unpleasant happen in the workplace.	0.360	0.687	0.739
25. I will still actively strive for the opportunity to be vaccinated under the many restrictions.	0.716	0.154	0.729
29. Even if I encounter troubles at work, I will still maintain an open-minded mood.	0.507	0.655	0.712
Cronbach's alpha	**0.97**	**0.93**	**0.91**

N=56

Variables		Mean	SD	Resilience mean differences (*P)*
Age (year)				
	<35 years old	3.31	0.590	**0.017 (Factor1)**
	>=35 years old	3.69	0.584	
Tenure				**0.018 VS. <7 years (Factor1)**
			0.417	
			0.724	
			0.590	
			712	0.233
			0.552	0.070
			0.710	
			0.686	0.078
			0.420	
Work Specialty				**0.019 (All 3 factors)**
	Non-oncology	3.65	0.585	
	Oncology	3.26	0.592	
Have you had CRN professional training and received certifications ?				0.558
	No	3.54	0.483	
	Yes	3.41	0.834	

Fixed factors to workplace resilience

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Components of the workplace resilience of CRNs during COVID-19 pandemic

(Jose, et al., 2020; Toscani et al.,2022)

Professionalism		Professional confidence
Strengthening competencies		Positive mindset at work
Research Quality & Patient Care		Self-perception positively

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Take home message

☑ Supporting and development of CRNs' well-being from organizations

☑ Long-term research schemes on the CRNs' workplace resilience are necessary for a post-pandemic workplace environment globally

☑ Future study: Large participants to test for a constructive validity scale development

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Q & A

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