Research Article

Associations between ICU-days and patient experiences and perceptions of clinical research in intensive care units: a mediation analysis

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Background: Clinical research is responsible for high-quality therapy in intensive care units (ICU). Patient experiences and perceptions are an integral part of the clinical research, but little is known about relationship between them. The objective of this study is to describe critically ill patient experiences and perceptions of clinical research in ICU.

Methods: Data were collected from 344 patients from 15 UK ICUs. A total of 344 critically ill patients (ICU-days: 0 day, 36.63%; 1 or more, 63.37%) completed the survey. Significant differences in the patient experiences and perceptions of clinical research in ICU were depicted with t test. The factor structures of patient experiences and perceptions of clinical research in ICU were explored by exploratory structural equation modeling and principal component analysis. Associations between socioeconomic factors and patient experiences and perceptions were explored with logistic regressions. Mediation analyses among patient experiences, patient perceptions, ICU-days, informed participation were performed with structural equation modeling.

Results: Most patients were males (56.31%). The factor structures of patient experiences and perceptions of clinical research in ICU were five and four, respectively. There were high proportions of good experiences and poor perceptions in the sample. Significant differences were observed in the patient perceptions of clinical research regarding informed participation in ICU. Patients with informed participation were less likely to have poor patient perceptions than without (OR: 0.46, 95% CI: 0.29-0.74). The relationship of ICU-days→informed participation was mediated moderated by age groups and gender. There were no significant mediation and moderation effects among informed participation, patient experiences, and patient perceptions.

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Conclusions: Our study offers several new insights regarding the role of informed participation in clinical research in patient experiences and perceptions in ICU. In addition, the findings suggest clinical research may benefit from socioeconomic factors of patients. Findings provide a basis for reflection on practice for specialist nurses, research teams, policymakers, and all with an interest in improvement in patient experiences and perceptions.

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Background

There has been an increase in the number of clinical research as result of the globalization trend [1][2]. Clinical research brings lasting benefits to health systems [3], establishes new treatments [4], derives a valid and meaningful scientific conclusion [5], and is primarily motivated by personal benefit [6]. Facilitators and barriers of participation in HIV [7][8][9], pediatric [10], gerontological [11] clinical research were reported. Barriers to participation in COVID-19 [12], Alzheimer's [13], diabetes [14] clinical research were reported. Often facing vexing dilemmas in critically ill patients, intensive care unit becomes an idealized place to embark on clinical research.

Regarding informed participation in clinical research, some factors negatively affect potential participants' understanding of clinical research included long informed consent forms [15] and misconceptions [16]. Some facilitators included altruistic reasons [17] and patient portals [18] to clinical research. There are cross-cultural differences of provisions on informed consent in clinical research in Germany, Poland, and Russia [19]. It is widely accepted and recognised that participant recruitment/invitations [20], inappropriate payment for participation in clinical research [21] sought to identify barriers to clinical research study. An early study explained the effect of race identity on intention to participate in clinical research [22]. But, little knowledge about other socioeconomic factors was reported.

Globally, the perceptions and attitudes towards clinical research were reported among the general public in Qatar [23], India [24], and Mauritius [25]. Patients' perspectives on clinical research were thought as useful and effective in older adults [26]. Attitudes and expectations of clinical research participants toward digital health and mobile dietary assessment tools were documented [27].

Participation in clinical trials positively influences the perception that participants have about pharmaceutical clinical research when compared to nonparticipants [28]. Therefore, poor perceptions in clinical research should be prevented.

Regarding ICU patient experiences, anxiety [29], stress [30], antimicrobial resistance [31], low and restricted self-determination [32], shortage in nutrition support [33], pain conditions [34] were observed. Clinical research can benefit from patient perspectives to inform trial design. Some factors influencing study design of clinical research have been previously reported. These factors included chairpersons' views in research ethics committees [35], suicide risk [36], ethical challenges [37][38][39].

The objective of the study was to assess ICU-days and patient experiences and perceptions of clinical research in intensive care units. This study hypothesized that associations between ICU-days and patient experiences and perceptions were mediated and moderated by analyses. With a publicly available survey data, this study would explore the factor structures of patient experiences and perceptions, mediating and moderating effect of socioeconomic factors in the relationship of ICU-days → informed participation, mediating and moderating effect of patient perceptions in the relationship of informed participation → patient experiences, and mediating and moderating effect of patient experiences in the relationship of informed participation→ patient perceptions.

Methods

Data source

Data collection was from 1 September 2016 to 31 May 2020 by the Project titled "The Perspectives Study: From evidence to guidance on patient recruitment to clinical research in intensive care units (https://reshare.ukdataservice.ac.uk/854286/)" [40]. An ethical analysis lead to the development of good practice guidance to enhance recruitment and consent processes for research in ICUs. Patients, relatives, and ICU staff were given separate versions of the survey. Each version included the same questions, with wording changed to reflect the respondents. Among the available 344 participants, surveyed sites were distributed as 1 (31.69%), 2 (2.33%), 3 (6.40%), 4 (14.24%), 5 (7.85%), 6 (3.20%), 7 (11.63%), 8 (4.07%), 10 (3.20%), 11 (4.07%), 12 (2.91%), 13 (5.52%), 14 (1.16%), and 15 (1.74%).

Main variables

Socioeconomic factors

The age options originally were distributed as 18-24, 25-34, 35-44, 45-54, 55-64, and 65-74 years. For statistical convenience, age options were integrated into young (18-34), middle (35-54), and old (55+) group. As for gender, the answers were male, female, and other. Here, the option "other" was considered as missing values. ICU-days was reflected by the question: "How long was your stay in the Intensive Care Unit (ICU)?" the response was a continuous variable from 0 to 70. For statistical convenience, ICU-days was categorized into groups: 0 and 1 or more.

Informed participation

Participation was reflected by the question: "Do you remember being asked to take part in a clinical research study in the ICU?" The response options were yes (=1), no (=2) and unsure (=3). Here, the response options of no (=2) and unsure (=3) were recoded as no (=0).

Patient experience of clinical research

Items of experience of clinical research studies in the ICU could be seen in Table 1. Response options were missing (=0), strongly disagree (=1), disagree (=2), neither agree nor disagree (=3), agree (=4), and strongly agree (=5). The reliability index of Experience of clinical research studies in the ICU in this sample is excellent (α = 0.9833).

The total score for the patient experiences was obtained by summing the 12 items ranges, with higher scores indicating greater experiences agreement. A mean score of 40.267 (SD= 5.029) for patient experiences, with possible scores ranging from 22 to 60 in the present study. Here, good experiences were defined as a score > median=40 on the scale.

Item	Content	Mean	Standardized errors
E1	Overall, the information about the clinical research study was clear.	1.430	2.010
E2	I was given little opportunity to ask questions about the clinical research study.	0.820	1.315
E3	It was hard to take in the information about the clinical research study.	0.913	1.444
E4	I was given enough time to think about whether or not I wanted to take part in the clinical research study.	1.349	1.941
E5	I felt pressure to take part in the clinical research study.	0.625	1.053
E6	The person who talked to me about the clinical research study was approachable.	1.459	2.057
E7	I was informed of the risks and benefits of the clinical research study.	1.265	1.852
E8	I trusted the person who talked to me about the clinical research study.	1.439	2.022
E9	Deciding whether or not to take part in the clinical research study was hard.	0.797	1.284
E10	The person who talked to me about the clinical research study was knowledgeable about it.	1.413	1.994
E11	I felt comfortable in making a decision about whether to take part in the clinical research study.	1.404	1.986
E12	I would be willing to take part in clinical research studies in the future.	1.134	1.802

Table 1. Experience of clinical research studies in ICU.

Perceptions of clinical research

Items of perceptions of clinical research in the ICU could be seen in Table 2. Response options were missing (=0), strongly disagree (=1), disagree (=2), neither agree nor disagree (=3), agree (=4), and

strongly agree (=5). The reliability index of Views on clinical research studies in the ICU in this sample is excellent (α = 0.8355).

The total score for the patient perceptions was obtained by summing the 11 items, with higher scores indicating greater perceptions agreement. A mean score of 36.910 (SD= 6.742) for patient perceptions, with possible scores ranging from 0 to 53 in the present study. Here, poor perceptions were defined as a score > median=38 on the scale.

Item	Content	Mean	Standardized errors
P1	All ICU patients should take part in clinical research studies, unless a doctor advises against it.	3.520	1.170
P2	Clinical research in the ICU is important to help other patients in the future.	4.279	0.873
P3	I assume that treatments given to me on the ICU have already been thoroughly tested in clinical research studies.	4.058	0.994
P4	I would only want to take part in a clinical research study if my own health might benefit.	2.544	1.256
P5	When an ICU patient is too ill to decide for themselves, it is acceptable for a member of their family to decide whether the patient should be included in a clinical research study.	3.654	1.170
P6	When an ICU patient is too ill to decide for themselves, and time is too short to contact a family member, it is acceptable for doctors to decide whether the patient should be included in a clinical research study.	3.331	1.276
P7	When an ICU patient is too ill to decide for themselves, and there are no known family members to contact, it is acceptable for doctors to decide whether the patient should be included in a clinical research study.	3.387	1.284
P8	When an ICU patient is too ill to decide for themselves, and there is a known family member, but they cannot be reached, then it is acceptable for doctors to decide whether the patient should be included in a clinical research study.	3.276	1.290
P9	When an ICU patient is too ill to decide for themselves, it is acceptable for a doctor to ask a family member over the phone for an opinion on whether the patient should be included in the clinical research study.	3.491	1.217
P10	If I was too ill to make a decision for myself, I would be upset if a doctor had consented on my behalf for me to be included in a clinical research study.	2.863	1.334
P11	If I was too ill to make a decision for myself, I would be upset if a family member had consented on my behalf for me to be included in a clinical research study.	2.506	1.273

Table 2. Perceptions of clinical research studies in ICU.

Statistical strategies

The statistical analyses in this study involved several steps. First, descriptive analysis is performed to display the frequency and percentage of age group, gender, informed participation, patient experiences, and patient perceptions. Second, independent samples t tests were used to compare means of patient experiences, and patient perceptions between sampled groups. Third, exploratory structural equation modeling (ESEM) was performed to explore potential structures of patient experiences and perceptions with Mplus v7.4. Subsequently, principal component analysis (PCA) in conjunction with varimax rotation with Kaiser's criterion is carried out using the Statistical Package for the Social Sciences (version 20.0; SPSS, Chicago, IL, USA) to explore the structure of patient experiences and perceptions. The Kaiser-Meyer-Olkin (KMO) coefficient and Bartlett's test would be measured to reflect suitable to conduct PCA. KMO values should be between 0 and 1 and larger than 0.7 which indicated the sampling is adequate. Fourth, associations between socioeconomic factors and patient experiences and perceptions were explored with logistic regressions. Finally, confirmatory factor analyses (CFA) were conducted using structural equation model for mediation and moderation models among ICU-days, informed participation, patient experiences, and patient perceptions. Here, goodness-of-fit indices of ESEM and structural equation modeling were chi-square/ degree of freedom ($\chi 2$/df), root mean square error of approximation (RMSEA), Akaike's information criterion (AIC), Bayesian information criterion (BIC), comparative fit index (CFI), Tucker–Lewis Index (TLI), standardized root mean-square residual (SRMR), and coefficient of determination (CD). Fit analyses were completed using Stata 14.0 (Stata Corporation, Texas, USA).

Results

Sample characteristics

The majority of the sample (36.63%) experienced 0 ICU day, followed by 1 day (6.69%), 2 days (11.34%), 3 days (6.10%), 4 days (8.43%), 5 days (5.81%), 6 days (2.91%), 7 days (3.49%), 8 days

(2.33%), 14 days (2.03%), 10 days (1.74%), 9 days (1.45%), 13 days (1.45%), and 21 days (1.45%). The average ICU days was 5.217 (±9.596) ranging from 0 to 70 days. Most of the sample (99.13%) experience 0 year. Among the available sample (n=344), 120(34.88%) take part in clinical research for one time, 216(62.79%) for 2 times, 8(2.33%) for 3 times. Among the available sample (n=324), 56(17.28%) were young, 133(41.05%) were middle, 135(41.67%) were older adults. Among the available sample (n=325), 142(43.69%) were females, 183(56.31%) were males. In table 3, there were no significant ICU-days differences in the case of age groups, gender, informed participation, experiences, and perceptions.

	ICU-days				χ2	P-value
	0		1 or more			
	N	%	N	%		
Age (N= 324)					1.6401	0.440
Young	22	6.79	34	10.49		
Middle	40	12.35	93	28.70		
Older	47	14.51	88	27.16		
Gender (N= 325)					1.0226	0.312
Female	51	15.69	91	28.00		
Male	56	17.23	127	39.08		
Informed participation (N= 344)					1.4041	0.236
No	77	22.38	147	42.73		
Yes	49	14.24	71	20.64		
Good experiences (N= 120)					0.0292	0.864
No	27	22.50	38	31.67		
Yes	22	18.33	33	27.50		
Poor perceptions (N= 344)					0.0054	0.942
No	70	20.35	122	35.47		
Yes	56	16.28	96	27.91		

Table 3. Sample characteristics by ICU-days.

Independent samples t tests

In Table 4, there were significant differences regarding item E9 on the basis of ICU-days. Except the item, there were no significant differences regarding items of patient experiences on the basis of gender and ICU-days.

Item	Group	Gender			ICU days		
		Female	Male	Differences	0	>=1	Differences
E1	Mean	4.080	4.188	-0.108	3.980	4.183	-0.204
	Obs	50	64		49	71	
E2	Mean	2.408	2.328	0.080	2.429	2.329	0.100
	Obs	49	64		49	70	
E3	Mean	2.542	2.762	-0.220	2.766	2.629	0.137
	Obs	48	63		47	70	
E4	Mean	3.840	4.016	-0.176	3.592	4.114	-0.522
	Obs	50	63		49	70	
E5	Mean	1.816	1.839	-0.022	1.936	1.771	0.165
	Obs	49	62		47	70	
E6	Mean	4.080	4.266	-0.186	4.041	4.282	-0.241
	Obs	50	64		49	71	
E7	Mean	3.469	3.810	-0.340	3.429	3.870	-0.441
	Obs	49	63		49	69	
E8	Mean	4.060	4.203	-0.143	3.959	4.239	-0.280
	Obs	50	64		49	71	
E9	Mean	2.408	2.175	0.234	2.625	2.114	0.511**

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Item	Group	Gender			ICU days		
		Female	Male	Differences	0	>=1	Differences
	Obs	49	63		48	70	
E10	Mean	3.940	4.188	-0.248	3.816	4.211	-0.395
	Obs	50	64		49	71	
E11	Mean	3.940	4.109	-0.169	3.918	4.099	-0.180
	Obs	50	64		49	71	
E12	Mean	3.413	3.789	-0.376	3.595	3.677	-0.082
	Obs	46	57		42	65	

Table 4. Mean-comparison tests of items of patient experiences in gender and ICU days

*** p<0.05.*

In Table 5, there were significant differences regarding item P4 and P10 on the basis of ICU-days. There were significant differences regarding items P1 to P9 on the basis of informed participation. Except those items, there were no significant differences regarding items of patient perceptions on the basis of gender, ICU-days, and informed participation.

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Item	Group	Gender			ICU days			Informed participation		
		Female	Male	Differences	0	>=1	Differences	No	Yes	Differences
V1	Mean	3.418	3.661	-0.243	3.520	3.586	-0.066	3.688	3.319	0.369***
	Obs	141	180		125	215		224	116	
V2	Mean	4.317	4.330	-0.013	4.290	4.352	-0.062	4.366	4.259	0.107**
	Obs	142	179		124	216		224	116	
V3	Mean	4.134	4.123	0.011	4.033	4.167	-0.134*	4.197	3.966	0.232***
	Obs	142	179		123	216		223	116	
V4	Mean	2.556	2.564	-0.008	2.823	2.431	0.392***	2.670	2.388	0.282**
	Obs	142	179		124	216		224	116	
V5	Mean	3.704	3.709	-0.005	3.710	3.690	0.020	3.795	3.509	0.286***
	Obs	142	179		124	216		224	116	
V6	Mean	3.479	3.298	0.180	3.352	3.381	-0.029	3.455	3.207	0.248**
	Obs	140	181		125	215		224	116	
V7	Mean	3.536	3.339	0.197	3.460	3.423	0.036	3.570	3.181	0.388***
	Obs	140	180		124	215		223	116	
V8	Mean	3.429	3.244	0.184	3.298	3.340	-0.041	3.444	3.095	0.349***
	Obs	140	180		124	215		223	116	
V9	Mean	3.479	3.547	-0.068	3.544	3.526	0.018	3.634	3.336	0.298***

	Obs	140	181		125	215		224	116	
V10	Mean	2.986	2.823	0.163	3.121	2.781	0.340**	2.906	2.905	0.001
	Obs	140	181		124	215		223	116	
V11	Mean	2.640	2.478	0.163	2.661	2.498	0.164	2.489	2.690	-0.201
	Obs	139	180		124	213		221	116	

Table 5. Mean-comparison tests of items of patient perceptions in gender, ICU days, and informed participation.

** p<0.1, ** p<0.05, *** p<0.01.*

Patient experiences of clinical research

Table 6 listed global models fit statistics for models fitting 1, 2, 3, 4, and 5 factors. Only the 5-factor structure was best structural fit of patient experiences ($\chi 2/df$ = 2.282, RMSEA=0.061, 90 CI: 0.035-0.087, p=0.221, CFI=0.998, TLI=0.990, and SRMR=0.005).

	χ2	***df***	**P-Value**	**χ2/df**	**RMSEA**	**90 CI**	**P-Value**	**CFI**	**TLI**	**SRMR**
1-factor	678.653	54	0.0000	12.568	0.183	0.171-0.196	0.000	0.929	0.913	0.046
2-factor	259.177	43	0.0000	6.027	0.121	0.107-0.135	0.000	0.975	0.962	0.009
3-factor	145.894	33	0.0000	4.421	0.100	0.084-0.117	0.000	0.987	0.974	0.008
4-factor	76.885	24	0.0000	3.204	0.080	0.060-0.100	0.007	0.994	0.983	0.004
5-factor	**36.508**	**16**	**0.0025**	**2.282**	**0.061**	**0.035-0.087**	**0.221**	**0.998**	**0.990**	**0.005**

Table 6. Summary of model fit information of patient experiences from ESEM.

df= degrees of freedom

In table 7, PCA was performed by 5 extracted factors with an eigenvalue greater than one accounted for 97.086% of total variance. Each rotated factor was considered to be composed of subtests with loadings bigger than 0.30. KMO measure of sampling adequacy was.961, which indicates adequate sample size for the factor analysis. Bartlett's test of sphericity was significant ($\chi 2$ =8653.876, df =66, p < 0.001). Factor loading after the rotation of each item is shown in Table 1. Accordingly, factor 1 with 3 items (E1, E5, and E9; alpha=0.93), factor 2 with 4 items (E2 and E8; alpha=0.84), factor 3 with 3 items (E3 and E4; alpha=0.98), factor 4 with 3 items (E6, E7, and E10; alpha=0.95), factor 5 with 4 items (E11 and E12; alpha=0.94) were obtained.

According to reference [41][42], patient experiences had substantial inter-rater reliability (combined Cohen's Kappa coefficient=0.6064, outcome 0 Kappa =0.9745, outcome 1 Kappa =0.1493, outcome 2 Kappa =0.1539, outcome 3 Kappa =0.3991, outcome 4 Kappa =0.4251, outcome 5 Kappa =0.4143). Thus, the scale could be a good tool to reflect patient experiences among the patients.

Item	Factors				
	1	2	3	4	5
E1	.813	.414	.215	.221	
E2	.424	.458	.682	.281	.211
E3	.474	.490	.352	.611	
E4	.845	.354	.226	.221	
E5	.361	.848		.254	
E6	.837	.365	.278		
E7	.853	.357	.230		
E8	.833	.361	.283	.219	
E9	.511	.714	.418		
E10	.837	.376	.244	.204	
E11	.833	.334	.273	.212	.228
E12	.714	.215	.231		.594

Table 7. Item loadings for factor analyses of patient experiences with varimax rotation.

Patient perceptions of clinical research

Table 8 listed global models fit statistics for models fitting 1, 2, 3, and 4 factors. Only the 4-factor structure was best structural fit of patient perceptions ($\chi 2/df$ =3.345, RMSEA=0.083, 90 CI: 0.059-0.107, p=0.012, CFI=0.995, TLI=0.984, and SRMR=0.003).

	$\chi 2$	*df*	P-Value	$\chi 2/df$	RMSEA	90 C.I.	P-Value	CFI	TLI	SRMR
1-factor	616.610	44	0.0000	14.014	0.195	0.181-0.208	0.000	0.930	0.913	0.048
2-factor	209.986	34	0.0000	6.176	0.123	0.107-0.139	0.000	0.978	0.965	0.008
3-factor	138.612	25	0.0000	5.544	0.115	0.097-0.134	0.000	0.986	0.969	0.004
4-factor	56.859	17	0.0000	3.345	0.083	0.059-0.107	0.012	0.995	0.984	0.003

Table 8. Summary of model fit information of patient perceptions of clinical research from ESEM.

df= degrees of freedom

In table 9, PCA was performed by 5 extracted factors with an eigenvalue greater than one accounted for 77.394% of total variance. Each rotated factor was considered to be composed of subtests with loadings bigger than 0.30. KMO measure of sampling adequacy was.826, which indicates adequate sample size for the factor analysis. Bartlett's test of sphericity was significant ($\chi 2$ =2141.325, df =55, p < 0.001). Factor loading after the rotation of each item is shown in Table 1. Accordingly, factor 1 with 3 items (P1, P2, and P3; alpha=0.68), factor 2 with 2 items (P4 and P5; alpha=0.24), factor 3 with 4 items (P6, P7, P8, and P9; alpha=0.93), factor 4 with 2 items (P10 and P11; alpha=0.78) were obtained. Thus, patient perceptions had fair inter-rater reliability (combined Cohen's Kappa coefficient=0.2321, outcome 0 Kappa =0.5906, outcome 1 Kappa =0.2269, outcome 2 Kappa =0.1066, outcome 3 Kappa =0.2909, outcome 4 Kappa =0.2224, outcome 5 Kappa =0.2897). Thus, the scale could be a good tool to reflect perceptions among the patients.

Item	Factors			
	1	2	3	4
V1	.420	.585		
V2		.224	.840	
V3		.789		.216
V4				.958
V5	.639	.338	-.226	.228
V6	.924			
V7	.927			
V8	.880		-.208	
V9	.773	.225		
V10	-.311		.817	
V11			.926	

Table 9. Item loadings for factor analyses of patient perceptions with varimax rotation.

Logistic regression

In Table 10, older group had high likelihood of patient perceptions compared with young group (Odds Ratio [OR]: 1.83, 95% confidence interval [CI]: 1.10-3.04). Patients with informed participation in clinical research had low likelihood of poor patient perceptions than without (OR: 0.46, 95% CI: 0.29-0.74).

	Good experiences (N=110)		Poor perceptions (N=319)	
	OR	95% CI	OR	95% CI
Age				
Young	1[reference]	1[reference]	1[reference]	1[reference]
Middle	0.68	0.23-2.00	1.21	0.73-2.01
Older	1.26	0.44-3.55	1.83**	1.10-3.04
Gender				
Female	1[reference]	1[reference]	1[reference]	1[reference]
Male	1.47	0.68- 3.18	0.75	0.49-1.16
ICU-days				
0	1[reference]	1[reference]	1[reference]	1[reference]
1 or more	0.85	0.38-1.88	0.85	0.55-1.32
Informed participation				
No	1[reference]	1[reference]	1[reference]	1[reference]
Yes	0.82	0.30-2.27	0.46***	0.29-0.74

Table 10. Associations between socioeconomic factors and patient experiences and perceptions.

** p<0.1, ** p<0.05, *** p<0.01.*

Mediation analyses

Regarding mediation analysis, fit statistic in Figure 1 was $\chi 2(0)=0.000$, RMSEA=0.000, 90% CI:0.000-0.000, p=1.000, AIC=2036.618, BIC=2081.800, CFI=1.000, TLI=1.000, SRMR=0.000, and CD=0.008. But, all the path coefficients between observed variables were not significant.

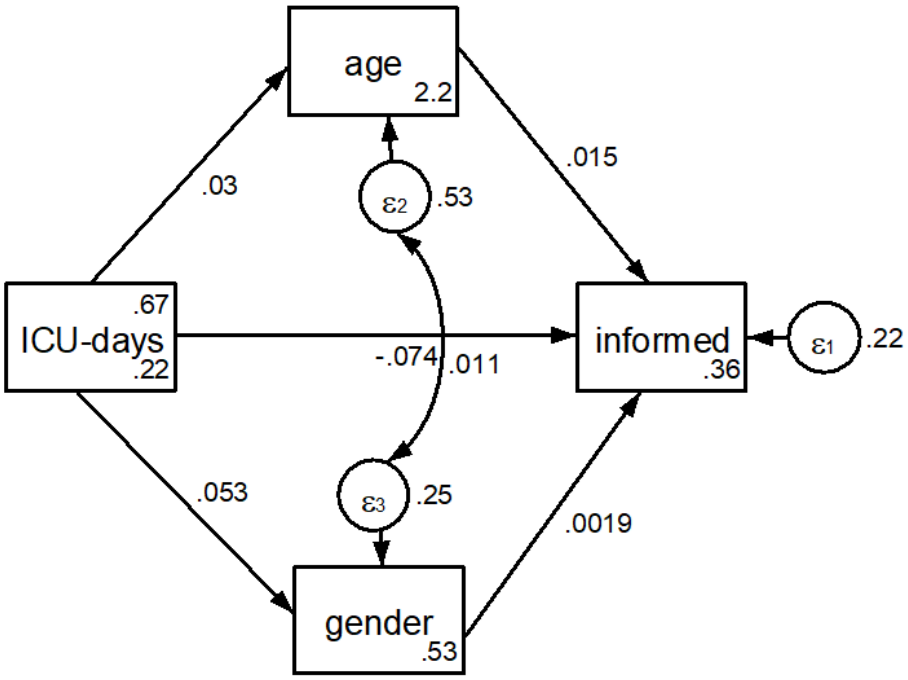

Figure 1. Simple mediation analysis.

Regarding moderation analysis, fit statistic in Figure 2 was $\chi 2(0)=0.000$, RMSEA=0.000, 90% CI: 0.000- 0.000, p=1.000, AIC=2040.618, BIC=2093.330, CFI=1.000, TLI=1.000, SRMR=0.000, and CD=0.006. But, all the path coefficients between observed variables were not significant.

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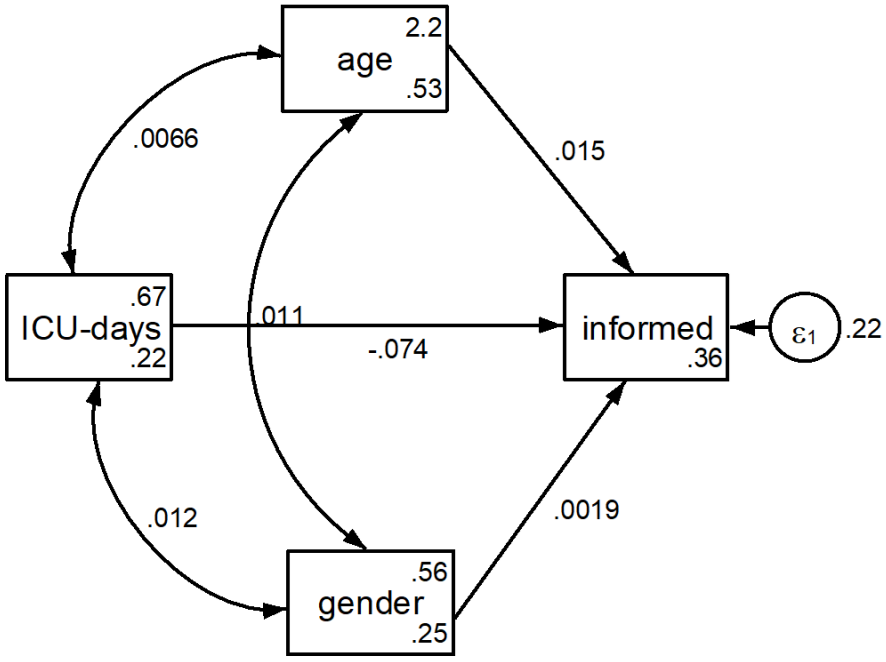

Figure 2. Simple moderation analysis.

In the structural model, the coefficients of observed variable: informed participation → E (4.092, p=0.000) and informed participation → P (-.211, p=0.003) were significant. In the measurement model, except the insignificant coefficient of P → P4 (-.050, p=0.699), all the other coefficients were significant (p=.000). Fit statistic in Figure 3 was $\chi 2(319)=1681.608$, p > chi2=0.000, RMSEA=0.116, 90% CI: 0.110-0.121, pclose=0.000, AIC=17998.841, BIC=18315.117, CFI=0.882, TLI =0.870, SRMR=0.076, and CD=0.008.

doi.org/10.32388/O8TDI3

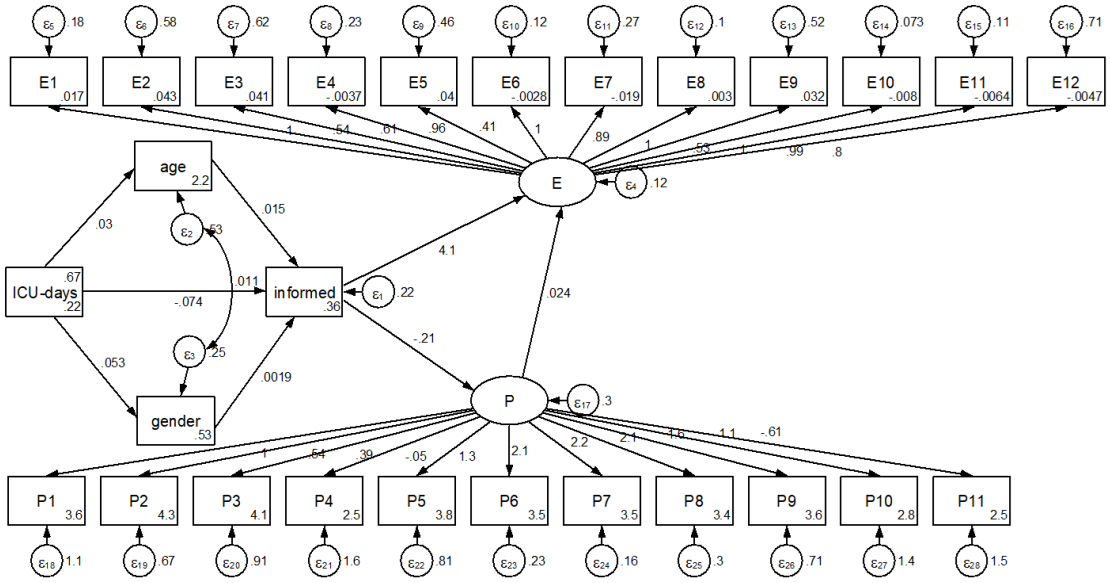

Figure 3. Informed participation with mediating factors→ E mediated by P

In the structural model, the coefficient of informed participation → E (4.087, p=0.000) was significant. In the measurement model, except the insignificant coefficient of P → P4 (-.050, p=0.699), all the other coefficients were significant (p=.000). The correlation coefficient of age ↔ gender was not significant (.011, p=0.595). Fit statistic in Figure 4 was $\chi 2(319)=1681.608$, p > chi2 =0.000, RMSEA=0.116, 90% CI: 0.110-0.121, pclose= 0.000, AIC=17998.841, BIC=18315.117, CFI=0.882, TLI =0.870, SRMR=0.076, and CD=0.008.

doi.org/10.32388/O8TDI3

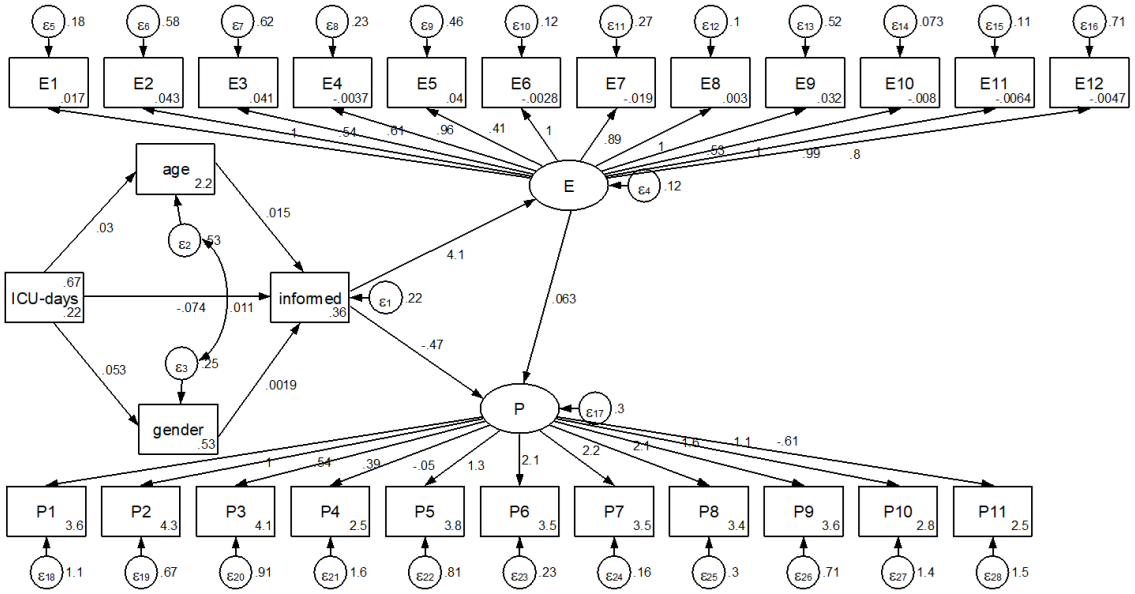

Figure 4. Informed participation with mediating factors → P mediated by E

In the structural model, the coefficients of informed participation → E (4.092, p=0.000) informed participation → P (-.211, p=0.003) were significant. In the measurement model, except the insignificant coefficient of P→P4 (-.050, p=0.699), all the other coefficients were significant (p=.000). The correlation coefficients of ICU-days ↔ age (.007, p=0.731), ICU-days ↔ gender (.012, p=0.376), age ↔ gender (.011, p=0.583) were not significant. Fit statistic in Figure 5 was $\chi 2(319)=1681.608$, p > chi2=0.000, RMSEA=0.116, 90% CI:0.110-0.121, pclose=0.000, AIC=18002.841, BIC=18326.648, CFI=0.882, TLI=0.871, SRMR=0.076, and CD=0.006.

doi.org/10.32388/O8TDI3

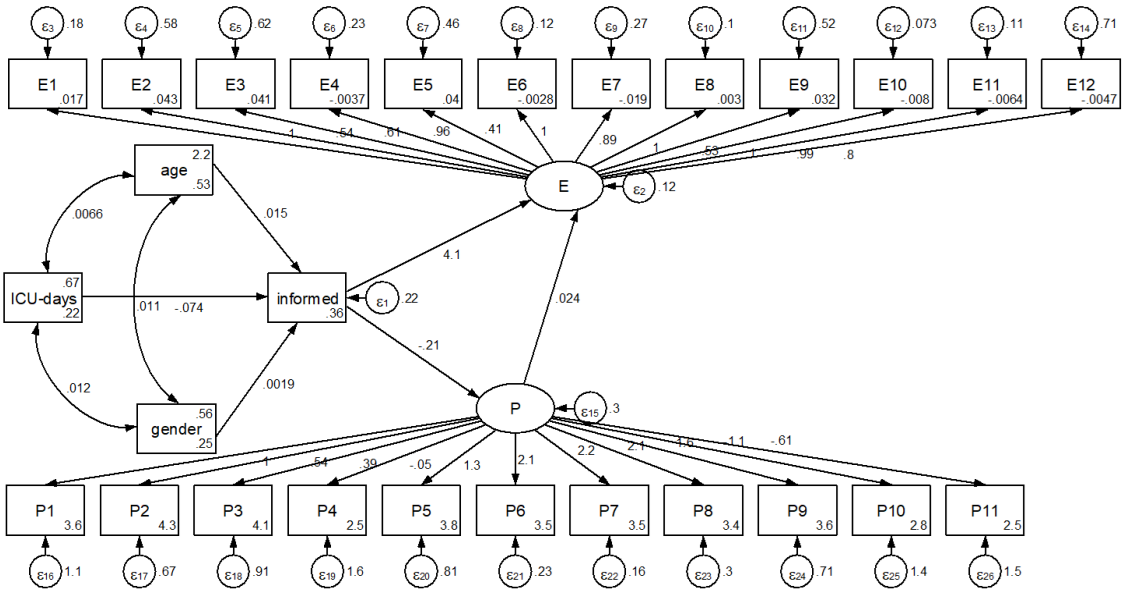

Figure 5. Informed participation with moderating factors→ E mediated by P

In the structural model, the coefficients of informed participation → E (4.087, *p*=0.000) was significant. In the measurement model, except the insignificant coefficient of P → P4 (-.050, *p*=0.699), all the other coefficients were significant (*p*=.000). The correlation coefficients of ICU-days ↔ age (.007, p=0.731), ICU-days ↔ gender (.012, *p*=0.376), age ↔ gender (.011, *p*=0.583) were not significant. Fit statistic in Figure 6 was $\chi 2(319)=1681.608$, p > chi2=0.000, RMSEA=0.116, 90% CI:0.110-0.121, pclose=0.000, AIC=18002.841, BIC=18326.648, CFI=0.882, TLI=0.871, SRMR=0.076, and CD=0.006.

doi.org/10.32388/O8TDI3

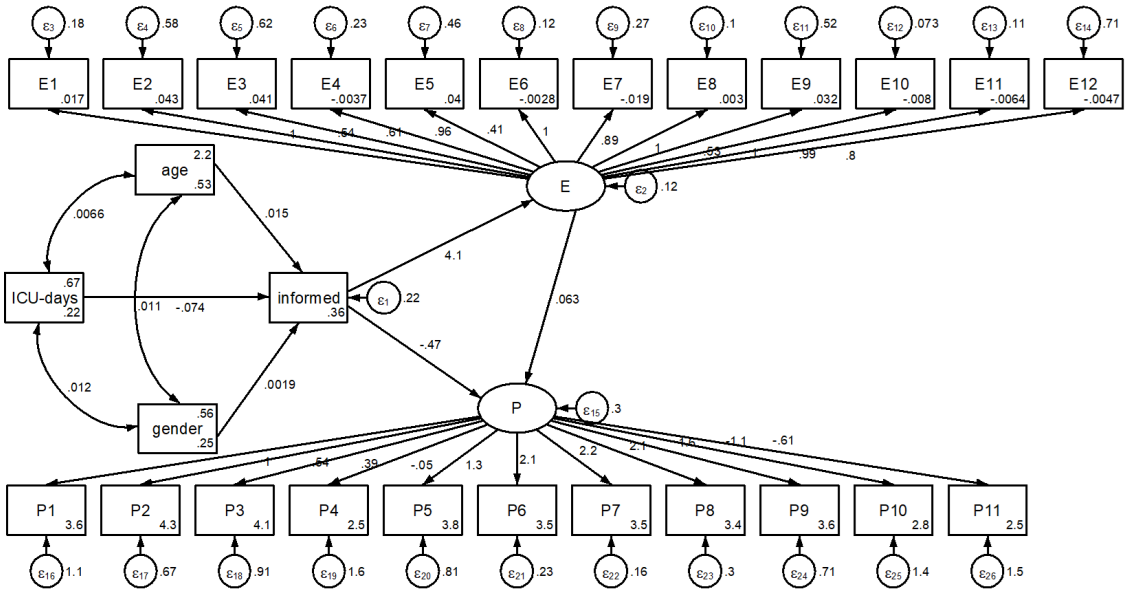

Figure 6. Informed participation with moderating factors → P mediated by E

Discussion

Summary

This study reported the factor structures of patient experiences and perceptions of clinical research in ICU. High proportions of good experiences and poor perceptions were reported in the sample. Informed participation had positive association with patient experiences and negative association with patient perspectives into their research. This study did not find significant mediating and moderating effect of socioeconomic factors in the relationship of ICU-days → informed participation, significant mediating and moderating effect of patient perceptions in the relationship of informed participation →patient experiences, and mediating and moderating effect of patient experiences in the relationship of informed participation→ perceptions.

Main explanations of key findings

Here are some of the main factors that contribute to patient participation in clinical research: markers of patient interest [43], patient involvement in the development of clinical research work [44], patients' knowledge regarding their illness experience [45], collaborative partnership and social values [46], and transparency and the standard of ethical reporting in nursing clinical research [47].

Poor clinical research could be partially explained by some prior literatures. Most clinical research is considered useless [48]. Limited knowledge on clinical research was observed in community advisory boards [49], clinical nurses [50], institutional review board members [51], and medical staff in the intensive care unit [52]. Even worse, part of clinical studies is ultimately not fully published in peer-reviewed journals [53] and lack of reproducible effects [54].

Poor perceptions of the patients in ICU could be explained by a large body of studies. Invalid informed consents [55] often preclude adequate understanding of prospective participants in clinical research. In most settings, patients do not understand informed consent what they have signed in clinical research [56]. Regarding patient's perceptions of clinical research, prior studies emphasize the role of clinical trial education [57], transparency and benefits [58]. Moreover, there are cross-cultural gaps of patients' attitudes toward clinical research [59].

Insignificant relationships between patient experiences and perceptions of clinical research could be partially explained by some early studies. Mismatch between patients' expectation and perceived outcomes [60] and contradictory opinions between patients and their legal representatives' concerning enrollment in a scientific study were often observed [61].

Good experiences of the patients in ICU could be explained by a series of studies. Some factors are barriers to high-quality outcomes in a clinical research including cost-effectiveness analysis [62], willingness to participate [63], mendacious informed consent [64], environmental contamination in the ICU wards [65], communication errors [66], pain management [67], medication errors [68][69], selection and information bias [70], poor quality and safety in intensive care [71], and serious drug induced reaction [72]. The patients in the clinical research were uncertain of study outcome and lack of feedback about results at the end of the study [73]. Some factors influencing generalization of outcomes of clinical research have been previously reported. These factors included gender bias in clinical research [74], patients' needs [75], and physicians' burnout in clinical research [76].

To the best knowledge of the author, the findings in this study enriched the process of prior studies. Methodologically, the items of patient perceptions in this study were less than those in an early study, while the dimensions of the scale were more [77]. With respect to sampled participants, this study was performed in adults rather than children and adolescents [78].

To the best knowledge of the author, this study missed some important information like the some prior studies. Compared to a previous study [79], this study did not provide the information of participant retention strategies. Moreover, this study did not provide the information of specific diseases of the patients like reference [80]. Moreover, this study was conducted in ICU rather than clinical research facility [81] or clinical trial unit [82]. Likewise, macro environmental factors like the COVID-19 pandemic [83] were not considered in the clinical research. Simultaneously, clinical research training among medical staff, clinician-scientists, and nurses was not reported.

Limitations

There are three limitations to note in this study. First, test-retest reliability or predictive validity estimates were unable to compute in this cross-sectional study. Second, patients in intensive care units were surveyed regarding informed participation. Therefore, patients' responses in ICU might be not accurate completely. Most patients in ICU lacked decision-making capacity for participation in clinical research [84].Numerous factors including ICU-acquired pressure injuries prevalence [85], ICU room configurations [86], heterogeneity [87], nurses' workload [88], medical errors [89], inadequate nutrition [90], and medication errors [91] might influence clinical research among critically ill patients. This is because clinical research can result in inadvertent harm to patients. Third, because the optimization could not converge to a local minimum, some SEMs with components in patient experiences and perceptions could not be analyzed.

Strengths

There are three strengths to note in this study. First, ESEM provided optimal factor structures of patient experiences and perceptions. Second with CFA, ICU-days, age, and gender were identified as limiting to informed participation in clinical research.

Direction for Future research

There were several directions for future research. First, further research on the associations among ICU-days, informed participation, patient experiences, and patient perceptions should consider medical staff and patients' relatives. Second, further study is warranted to determine the factor structures of patient experiences and perceptions of clinical research in ICU in a larger sample.

Policy implications

The findings of this study are crucial and may assist designing, developing, and manipulating clinical research in ICU. In addition, solutions to the challenges for clinical research should be on the basis of understanding of the patient needs for the quality of care. Well-designed clinical research needs to obtain positive patient experiences and perceptions.

Conclusions

The findings in this study may provide a challenge for clinical research in ICU from the angle of patients. Poor statistical relationships among ICU-days, informed participation, patient experiences, and patient perceptions were reported. The empirical outcomes in this study may provide useful insights for subsequent development of new clinical research. These findings suggest that future strategies to enhance the relationship between patient experiences and perceptions of clinical research in ICU may be accomplished through informed participation.

Abbreviations

- ICU: intensive care units
- aOR: Adjusted odds ratio
- 95% CI: 95% confidence interval

Declarations

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Ethics approval and consent to participate

The data adopted was from a publicly available survey dataset. All methods were carried out in accordance with relevant guidelines and regulations. Written informed consent was obtained from all participants before they agreed to participate in the study. Participants were informed that they could

leave the study at any time without penalty, and all personal information was kept confidential. Thus, it was not necessary to obtain ethical approval from the institutional review board at the author's institution.

Consent for publication

Not applicable.

Availability of data and material

https://reshare.ukdataservice.ac.uk/854286/

Competing Interests

The authors declared no potential conflict of interest with respect to the research, authorship and/or publication of this article.

Authors' contributions

MG designed the study, conceived the statistical analysis, and completed the original version. HYG searched literature, performed Tables and Figures, displayed the statistical outcomes, and participation in the discussion section under the tutorship of MG. The authors read and approved the final manuscript.

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