



Willingness to participate in clinical trials: A cross-sectional analysis in Ho Chi Minh City, Vietnam

[Disposición para participar en ensayos clínicos: Un análisis transversal en la ciudad de Ho Chi Minh, Vietnam]

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Abstract

Context: Clinical trial is an experiment on comparable groups of human beings which evaluates the efficacy of a treatment or medical intervention by comparing the effects with other testing treatments or control treatments. Clinical trials help develop alternative treatment solutions or a preventative method for disease as well as support participants with medical and healthcare services during the trial period. Other benefits of clinical trials include gaining information, ensuring health issues, detecting early disease symptoms, and reducing medical services costs.

Aims: To evaluate willingness to participate (WTP) in clinical trials (CT) in Ho Chi Minh city and examine the factors associated with it.

Methods: A cross-sectional study was conducted through the online sampling method and gathered 581 valid responses during two weeks in February 2022.

Results: Among 581 respondents, 71.6% stated they were willing to participate in CT, while 48.2% stated that they would let their family enroll. WTP in CT was higher in participants of younger age, single, not having children, healthy, and without chronic disease. Vietnamese age was associated with WTP in CT.

Conclusions: Assessing WTP in CT helps state management agencies, organizations and research institutes design suitable CT models and increase the voluntary participation rate in CT.

Keywords: clinical trial; Ho Chi Minh city; public; Vietnam; willingness to participate.

Resumen

Contexto: El ensayo clínico es un experimento en grupos comparables de seres humanos que evalúan la eficacia de un tratamiento o intervención médica comparando los efectos con otros tratamientos de prueba o tratamientos de control. Los ensayos clínicos ayudan a desarrollar una solución de tratamiento alternativa o un método preventivo para la enfermedad, así como también brindan apoyo a los participantes con servicios médicos y de atención médica durante el período de prueba. Otros beneficios de los ensayos clínicos incluyen obtener información, garantizar problemas de salud, detectar síntomas tempranos de enfermedades y reducir el costo de los servicios médicos.

Objetivos: Evaluar la disposición a participar (WTP) en ensayos clínicos (CT) en la ciudad de Ho Chi Minh y examinar los factores asociados con ella.

Métodos: Se realizó un estudio transversal a través del método de muestreo en línea y se recolectaron 581 respuestas válidas durante dos semanas en febrero de 2022.

Resultados: Entre 581 encuestados, el 71,6% afirmó estar dispuesto a participar en CT mientras que el 48,2% afirmó estar dispuesto a dejar que su familia se inscriba. La DAP en CT fue mayor en participantes de menor edad, solteros, sin hijos, sanos y sin enfermedad crónica. La edad vietnamita se asoció con WTP en CT.

Conclusiones: Evaluar la WTP en CT ayuda a las agencias estatales de gestión, organizaciones e institutos de investigación a diseñar modelos de CT adecuados y aumentar la tasa de participación voluntaria en CT.

Palabras Clave: Ciudad Ho Chi Minh; ensayo clínico; público; Vietnam; voluntad de participar.

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INTRODUCTION

A clinical trial (CT) is an experiment on comparable groups of human beings which evaluates the efficacy of a treatment or medical intervention by comparing the effects with other testing treatments or control treatments (Meinert, 2012; Ramalhinho and Castelo-Branco, 2021). Participants volunteer to register in CT to test these interventions, such as drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, and preventive care (World Health Organization, 2020). CT covers a wide range of topics using various methods such as mechanistic, exploratory or developmental, pilot or feasibility, interventional, or behavioral to answer the designed questions based on each topic (Kukreja et al., 2019). The purpose of CT is to differentiate the effectiveness and/or the side-effect-harmlessness of a new treatment from standard treatments (National Institute on Aging, 2020). CT may also enhance the quality of life for patients with life-threatening diseases or chronic health problems (National Institute on Aging, 2020).

When participants take part in CT, they have the opportunity to take an active role in their own health as well as contribute to medical and healthcare advancements (Novitzke, 2008). The goal of CT is also to help develop alternative treatment solutions if standard treatments are not available or not effective enough for patients (National Institute on Aging, 2017). Furthermore, CT produces a preventative disease method for healthy participants and/or supports participants with medical and healthcare services during the trial period (Locock and Smith, 2011; National Institute on Aging, 2017). Locock et al. mentioned in their previous study that CT was also a means for participants to collect information and ensure their health issues (Locock and Smith, 2011). CT participants may also receive treatment compliant with the treatment guidelines, and their altruistic desires should be fulfilled (Ali et al., 2015). In addition, CT helps participants detect early disease symptoms, increases access, and reduces the cost of medical services (Locock and Smith, 2011). Participants who were interviewed in a previous study in Russia stated that the benefits of CT included regular health check-ups and the opportunity to be provided with and explained about their test results or treatment recommendations (Zvonareva et al., 2015).

The low participation rate in CT is demonstrated by many different factors, including financial barriers, concern about the lack of information, resources to encourage registration, and maintenance of doctors and participants (Nipp et al., 2019). In addition, com-

munication gaps, mistrust of the medical system, and lack of awareness of CT were reported to be other reasons for the low participation rate (Harris et al., 1996). Another study also stated that additional monitoring tests, particularly invasion ones, which may be inconvenient for the patients or associated with potential morbidity, reduce the consent rate to participate in a CT (Comis et al., 2003). Moreover, participants would be less likely to enroll due to their lack of knowledge of risks and information transparency (Featherstone and Donovan, 2002). Conditional sampling criteria is also a barrier to CT, since it excludes certain population, resulting in the increased disparity between participants and actual patients (Nipp et al., 2019). Furthermore, the uncertain outcome of CT is a significant concern for patients and clinicians, directly influencing willingness to participate (WTP) and contributing to low CT enrollment rates (Nipp et al., 2019). More specifically, it is often difficult for them to assess the risk-benefit ratio, and may misjudge the probable severity related to the participation in CT, thereby reducing the WTP of participants (Nipp et al., 2019). A meta-analysis found that 55.6% of patients were unable to participate in CT because there was no available CT for the patient's cancer type and stage at the facility at that time being, 21.5% of patients were not eligible to participate, 14.8% of patients were eligible to participate but chose not to register and only 8.1% of patients were willing to participate (Unger et al., 2019). These studies had emphasized the importance of addressing barriers to CT participation in order to limit the shortage of registered participants (Unger et al., 2019).

Studies about WTP in CT have been carried out all over the world. The subject field was CT in general or specific healthcare interventions such as vaccines or treatments (Ahram et al., 2020; Almutairi et al., 2019; Al-Tannir et al., 2016; Chu et al., 2015; Farha et al., 2020; Goldman et al., 2021; Guedj et al., 2013; Kamath and As, 2014; Kaplan et al., 2015; Lim et al., 2017; Liu et al., 2020; Moorcraft et al., 2016; Raheja et al., 2018; Uhlmann et al., 2015). The CT participation rate in Jordan was 31.1%, while in Korea, this rate was only a quarter (Chu et al., 2015; Farha et al., 2020). In Saudi Arabia, 58% of respondents were willing to participate in CT if they were healthy (Al-Tannir et al., 2016). A study in the United States showed that males were more likely to enroll in CT than females (Raheja et al., 2018). Improving the accessibility to CT and ensuring the CT results in announcement might increase their WTP in vaccine CT (Raheja et al., 2018). Another study also reported no relationship between the race and participants' WTP in CT (Kaplan et al., 2015). In Jordan and Saudi Arabia, higher education

level was positively correlated with CT participation rate (Ahram et al., 2020; Almutairi et al., 2019).

Overall, many studies were determining WTP in CT and their contributing factors; however, no study in Vietnam has been found carrying out the issue. Therefore, the purpose of this study is to evaluate WTP in CT of the general public in Ho Chi Minh city (HCMC), Vietnam, and its associated factors. Moreover, this study might help state management agencies, organizations and research institutes design suitable CT models for Vietnamese and increase the voluntary participation rate in CT in the area in the future.

MATERIAL AND METHODS

Study design and setting

Ho Chi Minh City, located in southern Vietnam, is demonstrated in Fig. 1 (Vo et al., 2017). Based on Vietnamese census data in 2019, HCMC was the most populous city in Vietnam, with 8,993,082 people, accounting for 9.35% of the country's population. Calculating the sample size was conducted assuming 15% of participants were willing to participate in CT, 3% margin of error, and 95% confidence limits, resulting in 545 required participants (Almutairi et al., 2019). The inclusion criteria were above 18 years old, living in HCMC, being able to read and understand Vietnamese, and completing all the questions in the survey. In February 2022, a descriptive community-based cross-sectional survey was carried out on the general public in HCMC to evaluate their WTP in CT and gathered 581 valid responses.

Ethics statement

This study was approved by the committee of Pham Ngoc Thach University of Medicine and its ethics council (No. 653/TĐHYKPNT-HĐĐĐ). After providing a clear explanation, the purpose of the study was clearly demonstrated in the consent form given to all participants during the survey.

Instrument

A questionnaire was developed to collect participants' data about their WTP in CT based on a questionnaire from a previous study (Almutairi et al., 2019). The questionnaire includes 10 questions and is divided into three main parts (1) personal information (eight questions); (2) information about CT; (3) WTP in CT (two questions). The first part of the questionnaire consisted of gender, age, education level, occupation, healthcare career, health status, chronic disease and healthcare services evaluation in HCMC. The

second part included the definition, benefits and risks of participation in CT. The last part consisted of two qualitative questions about whether the respondent was willing to participate in CT and whether they were willing to let their family participate in CT. The questions are reviewed, clarified the meaning by the research team to resolve inconsistencies, ensure the clarity, intelligibility, appropriateness of the words used, comprehensibility and relevance of the items to the research topic. A pilot study was conducted with 15 Vietnamese people in which each person was asked how they understood the question, explained their answer, and detected the confusing or misleading words. The questionnaire was revised according to their comments to make it easier to understand.

Sampling method

In order to gather the required sample, our research team decided to use the online sampling method in which a survey form was designed based on the edited Vietnamese questionnaire to collect data. The first page of the form was a consent form ensuring the confidentiality of participants' information before moving on to the main questions. Those who chose "I do not agree to participate in the study" would not need to answer the main questions but would be forwarded to the end of the survey form containing a set of study materials as a gift after completing the survey. This form was shared by the researchers on social media for the period of two weeks in February 2022. Participants who were valid based on the inclusion criteria and completed the survey would have their responses recorded via an online sheet that automatically stores data from the survey form.

Statistical analysis

Microsoft Excel 2013 was used to collect the responses, filter, and store the data of the study, and then data were calculated with SPSS version 22.0. The demographic characteristics of participants were analyzed using descriptive statistics. Bivariate analyses were conducted to examine the significant differences between groups of participants in terms of WTP based on their demographic variables. Chi-square was conducted when the calculated expected value did not exceed 20%. On the other hand, if this value is greater than 20%, Fisher's exact test would be used instead. Binary logistic regression was employed to determine the demographic factors significantly associated with WTP in CT. Statistical significance was set at $p < 0.05$.

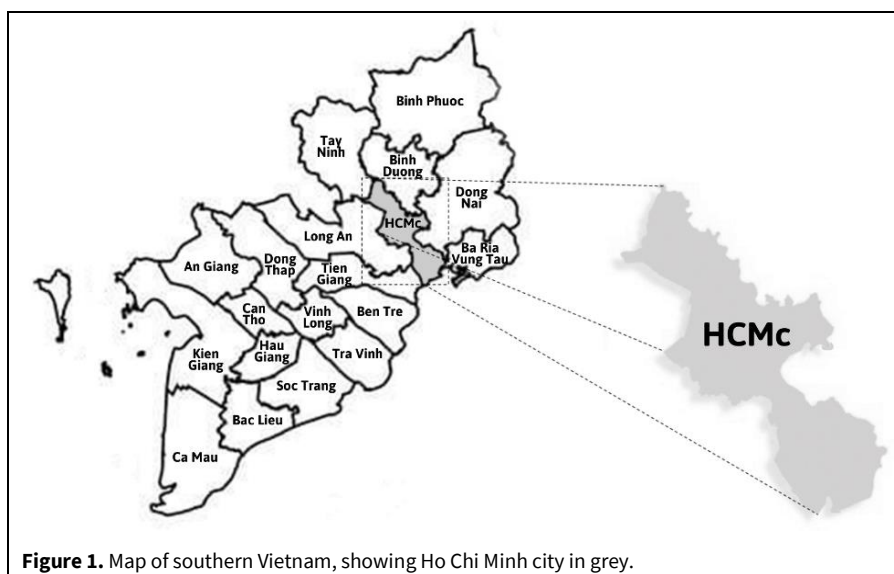


Figure 1. Map of southern Vietnam, showing Ho Chi Minh city in grey.

RESULTS

The demographic characteristics of the sample are demonstrated in Table 1. Among 581 respondents, 241 were male (41.5%) and 273 were over 25 years old (47.0%). The mean age of the participants was 30.9 ± 11.6 years old. The majority were graduates (81.4%), employed (81.8%), and had good health (79.5%). Nearly a fifth of the participants (24.8%) were healthcare employees, and very few had bad attitudes towards healthcare services in HCMC, accounting for no greater than 5.0%. Most respondents did not experience any chronic disease (72.5%). Of all chronic diseases included in the study, obesity was the most common, and Parkinson's was the least common, with a proportion of 8.3% and 0.3%, respectively.

Table 2 illustrates WTP in CT of participants in HCMC. The number of respondents willing to participate in CT was over twice as much as the number of the counter group. Specifically, 416 people (71.6%) were willing to participate in CT, while only 165 people (28.4%) were not willing to participate in CT. On the other hand, about half of the respondents (51.8%) were willing to let their families enroll in CT, indicating no significant differences between the number of those willing to let their families participate in CT and those not.

Table 3 shows the difference between groups regarding WTP in CT based on some demographic variables. It was found that younger participants from 18-29 were more willing to participate in CT ($n = 272$, 77.5%) comparing to older ones ($n = 144$, 62.6%) ($p < 0.001$). It was also recognizable that married respondents ($n = 124$, 64.9%) were less likely to accept enrollment in CT than single or divorced respondents ($n = 292$, 74.9%), with $p = 0.012$. In addition, parents (n

$= 144$, 64.9%) had lower WTP in CT than participants without children ($n = 272$, 75.8%) ($p = 0.005$). On the other hand, healthy participants ($n = 412$, 72.2%) and participants without chronic diseases ($n = 311$, 73.9%) were more willing to take part in CT than the ones who did not ($p = 0.035$ and $p = 0.049$, respectively).

A binary logistic regression model was constructed, showing the demographic factors significantly associated with participants' WTP in CT (Table 4). For every one-year increase in age, the odds ratio of WTP increased by 0.972 [95%CI=0.951 - 0.994] among respondents ($p = 0.014$). The analysis also found that other demographic independent variables included in the study did not influence the likelihood of accepting enrollment in CT in HCMC. These factors consisted of gender, education level, occupation, marital and health status, children, healthcare employee career, chronic disease, and evaluation of healthcare services in HCMC ($p > 0.05$).

DISCUSSION

To the best of our knowledge, there has not been any study about WTP in CT on the general public in Vietnam up until now; therefore, this study was conducted to evaluate WTP in CT of citizens in HCMC and examine the factors associated with it. Knowledge of WTP in CT of the general public may help researchers, organizations, and decision-makers in the country with their CT designs, increasing the CT participation rate in the future.

The CT enrollment rate in HCMC collected from the survey is noticeably high; specifically, 416 over 518 participants accept enrollment (71.6%).

Table 1. Demographic characteristics of the participants (n=581).

Characteristic	n	%
Gender		
Male	241	41.5
Age		
18-25	308	53.0
>25	273	47.0
Mean $\pm$ SD	30.9 $\pm$ 11.6	
Education level		
Undergraduate	50	8.6
Graduate	473	81.4
Post-graduate	58	10.0
Occupation		
Unemployed/Retired	106	18.2
Employed	475	81.8
Healthcare Employee		
No	437	75.2
Yes	144	24.8
Health status		
Bad	10	1.7
Normal	109	18.8
Good	462	79.5
Chronic disease		
None	421	72.5
Obesity	48	8.3
Asthma	12	2.1
COPD	4	0.7
Heart disease	10	1.7
Hypertension	35	6.0
Dyslipidemia	20	3.4
Diabetes	14	2.4
Musculoskeletal disorders	44	7.6
Parkinson	2	0.3
Others	30	5.2
Healthcare services evaluation in HCMc		
Very bad	5	0.9
Bad	17	2.9
Normal	211	36.3
Good	273	47.0
Very good	75	12.9

n: frequency; %: percentage; SD: standard deviation; HCMc: Ho Chi Minh City.

Table 2. Participants' willingness to participate in clinical trials (n=581).

Variable	n	%
Willing to participate in clinical trials		
No	165	28.4
Yes	416	71.6
Willing to let family participate in clinical trials		
No	301	51.8
Yes	280	48.2

n: frequency; %: percentage.

Table 3. Willingness to participate in clinical trials across sample characteristics.

Variable	WTP n (%)	Variable	WTP n (%)
Gender		Income	
Male	175 (72.6%)	Uncomfortable	130 (72.2%)
Female	241 (70.9%)	Comfortable	286 (71.3%)
	$\chi^2=0.208$; p=0.648		$\chi^2=0.050$; p=0.824
Age category		Health status	
18-29	272 (77.5%)	Bad	4 (40.0%)
≥ 30	144 (62.6%)	Normal/Good	412 (72.2%)
	$\chi^2=15.139$; p<0.001*		$\chi^2=4.997$; p=0.035*
Education level		Chronic disease	
Undergraduate	69 (67.6%)	None	311 (73.9%)
Graduate/Post-graduate	347 (72.4%)	Have chronic disease	105 (65.6%)
	$\chi^2=0.951$; p=0.329		$\chi^2=3.878$; p=0.049*
Marital status		Healthcare employee	
Single/Divorced	292 (74.9%)	No	305 (69.8%)
Married	124 (64.9%)	Yes	111 (77.1%)
	$\chi^2=6.243$; p=0.012*		$\chi^2=2.830$; p=0.093
Occupation		Healthcare services evaluation	
Unemployed/Retired	71 (67.0%)	Bad	15 (68.2%)
Employed	345 (72.6%)	Normal/Good	401 (71.7%)
	$\chi^2=1.361$; p=0.243		$\chi^2=0.131$; p=0.717
Children		n: frequency; %: percentage; χ^2 : Pearson Chi-square test; WTP: willingness to participate; * p statistically significant at < 0.05.	
None	272 (75.8%)		
Have children	144 (64.9%)		
	$\chi^2=8.017$; p=0.005*		

Table 4. Factors significantly associated with willingness to participate in clinical trials.

Variable	Willingness to participate		
	β (SE)	p	OR [95%CI]
Gender (male >< female)	-0.084 (0.194)	0.666	0.920 [0.629 - 1.345]
Age	-0.028 (0.011)	0.014*	0.972 [0.951 - 0.994]
Education level (undergraduate >< graduate/post-graduate)	-0.050 (0.252)	0.843	0.951 [0.580 - 1.560]
Occupation (employed >< unemployed)	0.139 (0.248)	0.577	1.149 [0.706 - 1.869]
Marital status (single >< married)	0.074 (0.311)	0.811	1.077 [0.586 - 1.979]
Children (none >< have children)	-0.131 (0.288)	0.649	0.877 [0.499 - 1.542]
Healthcare employee (no >< yes)	0.289 (0.230)	0.208	1.336 [0.851 - 2.096]
Income (uncomfortable >< comfortable)	0.069 (0.217)	0.751	1.071 [0.700 - 1.639]
Health status (bad >< good)	1.235 (0.678)	0.069	3.439 [0.910 - 12.992]
Chronic disease (don't have >< have)	-0.079 (0.223)	0.722	0.924 [0.596 - 1.430]
Healthcare services evaluation (bad >< good)	-0.032 (0.498)	0.948	0.968 [0.365 - 2.568]

β : coefficient of determination; SE: standard error; OR: odds ratio; CI: confidence interval; * p statistically significant at <0.05.

In a previous study carried out in Saudi Arabia, 58% of respondents indicated that they were willing to enroll in CT if they were healthy (Al-Tannir et al., 2016). Another study reported that CT registration rate in Jordan is only a quarter (Ahram et al., 2020). Farha et al. stated in another study in Jordan that only 31.1% of people were willing to volunteer in CT (Farha et al., 2020). In Korea, the participation rate was 25%, which was also quite low compared to the number in Vietnam (Chu et al., 2015). Therefore, it is recognizable that the CT participation rate in Vietnam was significantly higher than in Jordan and Korea. As a result, social differences such as geographical location, culture, economy, religion, politics, and health system of each country might have influenced WTP in CT of its citizens.

Based on the data analysis, a significant difference in CT enrollment rate was found between different demographic characteristics groups in Vietnam, Saudi Arabia and Korea. In Vietnam, younger participants from 18-29 were more willing to participate in CT (77.5%) than older ones (62.6%), with a $p < 0.001$. This result was also found in a Saudi Arabian study (75.7% versus 67.2%, respectively, $p = 0.015$) (Almutairi et al., 2019). However, in Korea, there was no significant difference in WTP in CT between younger and older participants ($p = 0.272$) (Chu et al., 2015). The older Vietnamese group may suffer more severe diseases than the younger group; therefore, participants over 29 years old might be concerned about their health when facing the risk factors of CT. This had led to the fact that they would be less willing to enroll in CT than younger ones. In contrast, due to medical and healthcare advancements in Korea, older Korean citi-

zens might have believed that the CT participation risk would not be severe to their health. As a consequence, there were no significant differences in WTP in CT between the age groups in Korea.

The demographic factors that affected WTP in CT were also different in each country. In Vietnam, age influenced WTP in CT ($p = 0.014$), but this was not true in Jordan ($p = 0.082$) (Farha et al., 2020). It was found in this study that the youth had higher WTP than the elder in Vietnam ($\beta = -0.028$). Indeed, the older Vietnamese get, the busier they become due to attending postgraduate education, focusing on their careers and taking care of their families. For this reason, older adults in Vietnam have more barriers toward CT than younger adults. Furthermore, it was reported that the gender of respondents in Jordan affected WTP in CT ($p = 0.041$), while Vietnamese gender did not affect WTP ($p = 0.666$) (Farha et al., 2020). In Farha's study, the Jordanian male participation rate in CT was 1.281 as much as that of females (Farha et al., 2020). This might be because Jordanian male was less afraid of the risk and safety concern of CT than female. Since Vietnamese women traditionally have had many great qualities such as patriotic, heroic, brave, benevolent, sentimental, faithful, and willing to sacrifice, they were not afraid of the risks of CT. This led to a similar value of WTP collected from both genders (72.6% for men and 70.9% for women). Moreover, while the Vietnamese education factor did not associate with WTP in CT ($p = 0.834$), the education level of Saudi Arabia did. Specifically, undergraduate respondents in Saudi Arabia were 1.75 more likely to enroll in CT than their counter group ($p = 0.035$) (Almutairi et al., 2019). Since information about CT is not

taught in schools and universities, most participants' knowledge comes from books, newspapers and social media, and education level in Vietnam has not influenced Vietnamese WTP in CT.

Some limitations have been observed in this study. First of all, because of the online sampling method, the sample size seemed to be skewed towards adolescents (53% of the participants were 18-25 years old). Furthermore, participants may have been eager to join CT; however, there is no guarantee that the decisions will remain unchanged due to specific conditions of the respondents, such as reallocation, time off work, disease suffered, and marriage. Another limitation of the study was that the findings in this study only act as a preliminary feasibility assessment based on the Vietnamese context; therefore, researchers, organizations, institutes, and research sponsors might need to investigate further relevant details, which were not included in this study.

CONCLUSION

This study was conducted in order to evaluate WTP in CT of participants in HCMC and examine the factors associated with it. Result showed that the participation rate was quite high (71.6%) while willingness to let their family enroll in CT was below average (48.2%). WTP in CT is higher in participants with younger age, single, not having children, healthy and without chronic disease. Findings also revealed that the younger the participants were, the more likely they were willing to participate in CT. These results should help governments, politics, organizations and institutes design more approaching and suitable CT, minimize the effects of barriers toward CT, increase the CT participation rate and improve treatment methods, contributing to Vietnamese health system advancements.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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AUTHOR CONTRIBUTION:

Contribution	Thoai ND	Tran TTB	Chau NDQ	Trung VQ
Concepts or ideas	x	x	x	x
Design	x	x	x	x
Definition of intellectual content	x			x
Literature search	x	x	x	
Experimental studies	x	x	x	
Data acquisition	x	x	x	
Data analysis	x	x	x	x
Statistical analysis	x	x	x	x
Manuscript preparation		x	x	x
Manuscript editing	x			x
Manuscript review	x	x	x	x

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