

Characteristics, attitudes, and the odds for positive attitude toward clinical trial: A study on Indonesian COVID-19 vaccine trial participants

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Abstract

Aims: This study was performed to understand the Indonesian population's characteristics and the factors that contribute to a more positive attitude toward participation in a clinical trial.

Methods: A cross-sectional survey was conducted involving 402 COVID-19 vaccine trial participants in Semarang, Indonesia, utilizing self-reporting questionnaires consisting of questions related to socio-demographic characteristics and statements in a 5-scaled Likert Scale to assess the attitude toward vaccine trial. The odds for positive attitude were analyzed using Ordinal Logistic Regression to obtain the odd-ratio and 95% confidence interval. The $P < 0.05$ was considered statistically significant.

Results: Most of the respondents were adults aged 22–64-year-old (89.30%), males (63.68%), married (77.61%), worked as an employee (59.70%), obtained information about the clinical trial from the Public Health Service (41.29%), had a low education level (40.80%), a low monthly income level (68.41%), with no previous participation in a clinical trial (90.80%). All respondents showed a good attitude toward the trial, with low education level, nonemployment status, fewer or no previous participation in clinical trials, and getting the information from the public health centers were the main predictors for better attitude toward vaccine trials.

Conclusion: There was a positive attitude toward vaccine trials in the Indonesian population. The positive attitude could be driven by having a low education level, nonemployment status, fewer or no previous participation in the clinical trial, and getting information from public health centers.

Keywords: Motivations, perceptions, positive attitude, vaccine clinical trial

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INTRODUCTION

A clinical trial is a critical part of drug and vaccine development. During the COVID-19 pandemic, finding

the proper treatment and effective vaccine as soon as possible resulted in an increased demand for clinical trials. Currently, 16 active COVID-19 vaccine clinical trials are

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conducted in Indonesia, and 9 other studies have been completed.^[1,2] Recruitment has always been a pivotal and challenging part of clinical research, and its planning is vital in achieving a scientifically sound study.^[3,4] Several studies have shown that some barriers may hinder participation in clinical trials, i.e., participants' beliefs, concern about safety, and lack of trust.^[5-7]

The ability of institutions conducting clinical trials to recognize the characteristics of the population where the clinical trial will be held and identify the factors that motivate potential subjects to participate and stay participating is crucial. A publication about the COVID-19 vaccine trials in Middle Eastern countries can identify two major factors influencing patients' continuous involvement. Those factors are the clinical trials' ethical conduct and the desire to protect the family from the disease.^[8]

A study published by Williams *et al.* stated that premature trial termination is mainly caused by a poor accrual rate, which indicates that the study has insufficient tactics and strategies in its recruitment process.^[9] Moreover, literature and studies mention that low participant retention, underrepresentation of specific groups, and unreached target size are some consequences of poorly executed recruitment.^[9-11]

Our study aims to give an update on the characteristics of participants of vaccine clinical trials from the Indonesian population and their general attitude toward clinical trials and to identify the characteristics which lead to a more positive attitude toward the trial. The findings will hopefully identify overarching factors to help strategize clinical trial recruitment. This observation does not examine the impact of the COVID-19 pandemic on community decisions.

METHODS

Study design and setting

A cross-sectional survey was conducted utilizing self-reporting questionnaires in the Indonesian language. The study was held at four Central Java medical centers, namely Mranggen, Demak; Pecangaan, Jepara; Pringapus, Ungaran; and Semarang. The data were gathered from October to December 2022.

Instrument development

Questionnaire statements were generated through Literature Research and experts' opinions. A validated questionnaire consists of 20 statements covering four aspects: Normative Beliefs, Behavioral Perspectives, Compliance Motives, and Personal Interests. These aspects were derived and

simplified from the Clinical Research Involvement Scale by Frew *et al.*, with the definition as follows: normative beliefs are defined as participatory intentions against social norms prevailing in the community.^[12] It picked several overarching issues regarding Indonesian norms. Behavioral perspectives encompass participant behavior or internal drives that impact their attitude toward clinical trial participation. Compliance motives revolve around relatives' pressures, whether from family, friends, employers or even the organization they were involved in, also external drives that make participants remain in the trial. Personal Interests embody the personal agenda or relevance, which may result in a willingness to participate in the research, and reasoning may extend to specific outcomes or expectations. For each aspect, several statements were developed, and a Likert Scale with responses ranging from "strongly disagree," "disagree," "neutral," "agree," and "strongly agree" was used.

Demographic information included gender, domicile, employment, ethnicity, religion, marital status, education level, salary, the time needed to reach the trial location, frequency of trial participation, and the trial source of information.

After the questionnaire was formulated, a panel of experts conducted a face validity test. Validation and reliability tests were conducted on the 49 questionnaires with no correlation coefficient of items fell under 0.3. The reliability of the questionnaire was estimated using Cronbach alpha (α). The reliability score of 0.897 was obtained through a statistical calculation using SPSS using the threshold of 0.6. (IBM Statistics for MacOS (Version 27.0) (IBM Corp., New York, USA).

Targets, sample size calculation, and sampling strategy

The population target was those who participated as a subject in a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine clinical trial. For the sample size calculation, according to the World Health Organization, 1044 trials were conducted in Indonesia so far.^[13] Assuming that hundreds to 4000 subjects were enrolled per trial, we considered the study population to be infinite. The size estimation was calculated using an online calculator Raosoft (Raosoft Inc., Seattle, Washington, USA) with a confidence interval (CI) of 95% and a margin of error of 5%.^[14] It was suggested that our study should have at least gather 377 participants to fill out the questionnaire.

The study was conducted in several sites within Central Java and West Lombok province. Therefore, a nonprobability, convenient sampling technique was employed. The sampling technique was also considered due to the need for

more data on the number of clinical trial past and present subjects and the access to currently running a trial in the other regions in Indonesia.

Data collection

The questionnaire was distributed to 403 subjects of Semarang Centre from phases 1–3 of the clinical trials within the aforementioned sites, which had to be completed and collected within the same day. Consent was taken from those who agreed to participate before the data collection. This indicates that the participant had read the study information provided and had been briefed by one of the study team.

Data analyses

The data were analyzed using the licensed IBM Statistics for MacOS (Version 27.0) (IBM Corp., New York, USA). A descriptive analysis was reported as a result. Furthermore, the odds for a positive attitude toward clinical trial were analyzed with an Ordinal Logistic Regression to obtain the odd-ratio (OR) and 95% CI. The $P < 0.05$ was considered statistically significant. The analysis was done to see the odds for a positive attitude toward clinical trial, which characteristic(s) is (are) likely to have a more positive attitude in joining and staying in the clinical trial. It is assumed that the higher the Likert score, the more respondents show a positive attitude.

Ethical considerations

This study had been approved by the Ethical Committee of Health Research with the Ethical Clearance number 372/EC/KEPK/FK-UNDIP/X/2022.

RESULTS

Subjects characteristics

From 403 questionnaires, one questionnaire was incomplete. The remaining 402 were used for analysis. The characteristics of the subjects are presented in Table 1.

Most of the subjects were adults aged 22–64-year-old (89.30%), males (63.68%), had an elementary school or below education (40.80%), worked as an employee (59.70%), had a low monthly income level (<1,500,000 rupiah/month; 68.41%), married (77.61%), with a short commuting time from their house to the trial site (<15 min; 58.46%), had no previous participation in a clinical trial (90.80%), and obtained information about the clinical trial from the primary health care (41.29%).

Attitudes toward vaccine clinical trial

Attitudes of subjects toward clinical trial and participation in a clinical trial are grouped into several aspects, as

Table 1: Subject characteristics

Variables	Frequency (%)
Age group	
Young adult 18–21 years old	23 (5.72)
Adult 22–64 years old	359 (89.30)
Elderly 65 or above	20 (4.98)
Gender	
Male	256 (63.68)
Female	146 (36.32)
Education level	
Elementary school or below	164 (40.80)
Junior high school	113 (28.11)
Senior high school	110 (27.36)
University graduate	15 (3.73)
Occupation	
Employee	240 (59.70)
Nonemployee	134 (33.33)
Jobless	28 (6.97)
Monthly income	
Low	275 (68.41)
Middle low	113 (28.11)
Middle up	14 (3.48)
Domicile	
Demak	209 (51.99)
Semarang regency	135 (33.58)
Semarang city	56 (13.93)
Boyolali	1 (0.25)
Jepara	1 (0.25)
Ethnicity	
Java	401 (99.75)
Batak	1 (0.25)
Marital status	
Single	70 (17.41)
Married	312 (77.61)
Divorced	20 (4.98)
Commuting time (min)	
<15	235 (58.46)
15–30	98 (24.38)
>30	69 (17.16)
Previous participation in the clinical trial	
Never	365 (90.80)
Yes, once	26 (6.47)
Yes, more than once	11 (2.74)
Source of information	
Primary health care (Puskesmas)	166 (41.29)
Head of village/district	98 (24.38)
Family/friends	98 (24.38)
WhatsApp group	24 (5.97)
Other	16 (3.98)

explained in the methods section and presented in Table 2.

In all of the statements that cover most aspects, respondents had positive attitudes toward the vaccine clinical trial.

Odds for positive attitude toward vaccine clinical trial

The results of analysis on the odds for positive attitudes are shown in Table 3a-c.

Education level is related to all aspects toward a more positive attitude, as seen in statements 2 and 5 of behavioral perspective aspects, statements 1 and 3 of normative beliefs aspect, statements 1 and 5 of the compliance motive aspect,

Table 2: Attitudes toward vaccine clinical trial

Statement number	Variable	Number of subjects (%)
1	Behavioral perspectives	
	I feel that taking part in clinical trials is a good and useful thing	
	Strongly disagree	3 (0.7)
	Disagree	5 (1.2)
	Neutral	38 (9.5)
	Agree	254 (63.2)
2	I feel that participating in clinical trials can protect my family from COVID-19	
	Strongly disagree	4 (1.0)
	Disagree	2 (0.5)
	Neutral	34 (8.5)
	Agree	262 (65.2)
	Strongly agree	99 (24.6)
3	If I take part in a clinical trial, then my friends/family/neighbors will	
	Strongly disagree	5 (1.2)
	Disagree	22 (5.5)
	Neutral	109 (27.1)
	Agree	212 (52.7)
	Strongly agree	52 (12.9)
4	I understand the purpose of this clinical trial	
	Strongly disagree	3 (0.7)
	Disagree	11 (2.7)
	Neutral	58 (14.4)
	Agree	291 (72.4)
	Strongly agree	37 (9.2)
5	I am interested in taking part in clinical trials because I believe the side effects of the products are mild and harmless	
	Strongly disagree	4 (1.0)
	Disagree	5 (1.2)
	Neutral	54 (13.4)
	Agree	261 (64.9)
	Strongly agree	78 (19.4)
1	Normative beliefs	
	I took part in clinical trials because I believed that the products provided were effective and beneficial	
	Strongly disagree	3 (0.7)
	Disagree	5 (1.2)
	Neutral	38 (9.5)
	Agree	277 (68.9)
2	I am involved in clinical trials because the vaccine being tested is halal	
	Strongly disagree	3 (0.7)
	Disagree	5 (1.2)
	Neutral	43 (10.7)
	Agree	262 (65.2)
	Strongly agree	88 (21.9)
3	Every new drug/vaccine must first be tested for its safety and effectiveness on a small scale	
	Strongly disagree	4 (1.0)
	Disagree	6 (1.5)
	Neutral	43 (10.7)
	Agree	233 (58.0)
	Strongly agree	115 (28.6)
1	Compliance motives	
	I took part in a clinical trial because they provide me with insurance	

Table 2: Contd....

Statement number	Variable	Number of subjects (%)
	Strongly disagree	3 (0.7)
	Disagree	52 (12.9)
	Neutral	85 (21.1)
	Agree	208 (51.7)
	Strongly agree	51 (12.7)
2	The research team was very informative, responsible, and easy to contact for answers	
	Strongly disagree	3 (0.7)
	Disagree	5 (1.2)
	Neutral	31 (7.7)
	Agree	276 (68.7)
3	I worry about what people will think if I stop in the middle of my research	
	Strongly disagree	20 (5.0)
	Disagree	129 (32.1)
	Neutral	94 (23.4)
	Agree	134 (33.3)
4	The clinical trial procedure is easy to understand	
	Strongly disagree	3 (0.7)
	Disagree	10 (2.5)
	Neutral	48 (11.9)
	Agree	292 (72.6)
5	I am interested in taking part in clinical trials because of advice from religious leaders/traditional/village leaders	
	Strongly disagree	10 (2.5)
	Disagree	64 (15.9)
	Neutral	80 (19.9)
	Agree	203 (50.5)
6	I am interested in taking part in clinical trials because of recommendations from family/friends	
	Strongly disagree	7 (1.7)
	Disagree	52 (12.9)
	Neutral	86 (21.4)
	Agree	210 (52.2)
7	I am interested in participating in this clinical trial because the explanation from the researcher is very clear	
	Strongly disagree	3 (0.7)
	Disagree	5 (1.2)
	Neutral	50 (12.4)
	Agree	274 (68.2)
1	Personal interests	
	I am willing to participate in a clinical trial to be compensated for the risk and time spent	
	Strongly disagree	3 (0.7)
	Disagree	30 (7.5)
	Neutral	77 (19.2)
2	I am participating in a clinical trial of a COVID-19 vaccine so I can apply for jobs and travel	
	Strongly disagree	5 (1.2)
	Agree	241 (60.0)
	Strongly agree	50 (12.4)
	Strongly disagree	5 (1.2)

Contd...

Contd...

Table 2: Contd....

Statement number	Variable	Number of subjects (%)
3	Disagree	66 (16.4)
	Neutral	72 (17.9)
	Agree	212 (52.7)
	Strongly agree	47 (11.7)
	I took part in clinical trials because I wanted to help government programs in vaccine production	
4	Strongly disagree	3 (0.7)
	Disagree	8 (2.0)
	Neutral	35 (8.7)
	Agree	286 (71.1)
	Strongly agree	70 (17.4)
5	I took part in clinical trials because I wanted to contribute to the development of science	
	Strongly disagree	4 (1.0)
	Disagree	10 (2.5)
	Neutral	54 (13.4)
	Agree	276 (68.7)
5	Strongly agree	57 (14.2)
	I am interested in taking part in clinical trials because this vaccine is domestically produced	
	Strongly disagree	3 (0.7)
	Disagree	16 (4.0)
	Neutral	61 (15.2)
	Agree	248 (61.7)
	Strongly agree	71 (17.7)

and statements 1 of personal interest aspect. In general, it is shown that a lower education level is related to a more positive attitude toward the vaccine trial. Behavioral perspective 1 and 5, normative belief 1 and 3, compliance motive 1 and 5, and personal interest 1's OR and 95% CI consecutively are 0.660 (95% CI: 0.516–0.844), 0.608 (95% CI: 0.478–0.773), 0.612 (95% CI: 0.474–0.790), 0.724 (95% CI: 0.574–0.912), 0.733 (95% CI: 0.590–0.909), 0.725 (95% CI: 0.587–0.895), and 0.656 (95% CI: 0.522–0.825).

Occupation group Nonemployee and Jobless was related with a more positive attitude in multiple statements covering normative and personal interest aspects, as well as median normative aspect and median personal interest aspect. The statements included the belief that a new drug should be tested for safety and efficacy on a small scale before marketing, on the contribution to the government's program and for the development of science. Normative belief 1, personal interest 3 and personal interest 4's OR and 95% CI consecutively are 1.632 (95% CI: 1.155–2.308), 1.496 (95% CI: 1.030–2.173), and 1.584 (95% CI: 1.100–2.281).

Fewer or no previous participation in clinical trials seemed to be related to a more positive attitude, as shown by the significant *P* value on statements 2 and 5 of the behavioral perspective, which mentioned that joining the

trial could help protect the family and the belief of the product's safety. Significant values were also observed in the compliance motive aspect, statements 2 and 7, about the availability of clinical trial personals and the clarity of the trial given by clinical trial personals. Behavioral perspective 2 and 5, compliance 2 and 7's OR and 95% CI, consecutively are 0.568 (95% CI: 0.333–0.970), 0.561 (95% CI: 0.333–0.943), 0.557 (95% CI: 0.323–0.961), and 0.566 (95% CI: 0.335–0.956).

The source of information about the vaccine clinical trial seemed to affect the positive attitude toward the trial. Respondents who got the information from medical centers or the head of the village showed a more positive attitude in statements covering normative and personal interest aspects. The statements included those about belief in the safety and efficacy of the vaccine, the contribution to the government's program and the contribution to the development of science. Normative belief 1, personal interest 3, and personal interest 4's OR and 95% CI consecutively are 0.828 (95% CI: 0.695–0.986), 0.819 (95% CI: 0.675–0.994), and 0.818 (95% CI: 0.678–0.986).

The age group was related to a higher positive attitude in 1 statement of compliance motive aspect OR 1.909 (95% CI: 1.043–3.495) about the availability of insurance. Female gender seemed to be related to a more positive attitude also in 1 statement of behavioral perspective aspect, which mentioned the vaccine side effect, OR 1.651 (95% CI: 1.036–2.630). Being married was found to be related to a more positive attitude from behavioral perspective, which is about understanding the trial's purpose. OR 1.794 (95% CI: 1.064–3.026). Respondents with commuting times <15 min seemed to have a more positive attitude on compliance motive, particularly where the health insurance is present. OR 0.770 (95% CI: 0.597–0.992). The monthly income level was not related to any aspect toward a more positive attitude.

DISCUSSION

Subjects recruitment in a clinical trial has always been challenging, particularly in vaccine clinical trials where the subjects are healthy people. Maintaining the subject's compliance with the clinical trial schedule is another challenge that must be addressed. Understanding the characteristics of the population and identifying factors that contribute to a more positive attitude toward participation in a clinical trial is essential to ensure the completion and success of a trial.^[15] In a more extensive application, understanding these factors will help the

Table 3a: Odds of age group, gender, and occupation group for a positive attitude toward clinical trial

Variables	Age group		Gender		Occupation group	
	Significant	OR (95% CI)	Significant	OR (95% CI)	Significant	OR (95% CI)
Behavioral perspectives aspect						
Statement 1	0.140	1.637 (0.850–3.151)	0.613	0.888 (0.562–1.405)	0.292	1.205 (0.852–1.704)
Statement 2	0.142	1.657 (0.844–3.252)	0.759	0.930 (0.583–1.482)	0.119	1.321 (0.931–1.874)
Statement 3	0.434	1.289 (0.683–2.431)	0.824	1.051 (0.681–1.621)	0.897	0.979 (0.706–1.357)
Statement 4	0.204	1.570 (0.782–3.151)	0.553	0.859 (0.519–1.421)	0.485	1.144 (0.784–1.668)
Statement 5	0.458	1.287 (0.661–2.505)	0.035	1.651 (1.036–2.630)	0.201	1.261 (0.884–1.798)
Normative beliefs aspect						
Statement 1	0.334	1.404 (0.705–2.796)	0.367	1.246 (0.772–2.012)	0.323	1.200 (0.836–1.720)
Statement 2	0.247	1.475 (0.764–2.848)	0.41	1.216 (0.763–1.937)	0.276	1.220 (0.853–1.743)
Statement 3	0.18	1.550 (0.817–2.942)	0.085	0.674 (0.431–1.056)	0.006	1.632 (1.155–2.308)
Compliance motives aspect						
Statement 1	0.036	1.909 (1.043–3.495)	0.942	0.984 (0.642–1.509)	0.876	0.975 (0.706–1.346)
Statement 2	0.192	1.573 (0.796–3.110)	0.474	1.192 (0.737–1.930)	0.113	1.348 (0.932–1.951)
Statement 3	0.197	0.667 (0.361–1.234)	0.071	1.459 (0.969–2.196)	0.974	0.995 (0.735–1.348)
Statement 4	0.192	1.600 (0.790–3.239)	0.813	1.063 (0.643–1.758)	0.360	1.195 (0.816–1.750)
Statement 5	0.749	1.104 (0.604–2.017)	0.981	0.995 (0.653–1.516)	0.923	0.984 (0.713–1.359)
Statement 6	0.361	1.317 (0.729–2.378)	0.477	1.170 (0.759–1.804)	0.851	0.968 (0.694–1.351)
Statement 7	0.319	1.413 (0.716–2.789)	0.147	1.429 (0.882–2.316)	0.173	1.291 (0.894–1.864)
Personal interests aspect						
Statement 1	0.132	1.631 (0.863–3.082)	0.948	1.015 (0.651–1.582)	0.852	1.033 (0.735–1.452)
Statement 2	0.909	1.037 (0.556–1.934)	0.266	0.785 (0.513–1.202)	0.790	0.957 (0.694–1.321)
Statement 3	0.256	1.511 (0.741–3.080)	0.359	0.794 (0.486–1.300)	0.034	1.496 (1.030–2.173)
Statement 4	0.123	1.711 (0.864–3.387)	0.410	0.817 (0.506–1.321)	0.013	1.584 (1.100–2.281)
Statement 5	0.354	1.352 (0.715–2.557)	0.624	0.892 (0.564–1.410)	0.151	1.298 (0.909–1.853)

Grey shadings show cells with a $P < 0.05$. OR=Odds ratio, CI=Confidence interval

Table 3b: Odds of education level, salary level, and marital status for positive attitude toward clinical trial

Variables	Education		Salary		Marital status	
	Significant	OR (95% CI)	Significant	OR (95% CI)	Significant	OR (95% CI)
Behavioral perspectives aspect						
Statement 1	0.071	0.805 (0.636–1.019)	0.776	0.946 (0.647–1.383)	0.421	1.221 (0.751–1.983)
Statement 2	0.001	0.660 (0.516–0.844)	0.605	1.110 (0.748–1.648)	0.782	0.933 (0.571–1.526)
Statement 3	0.055	0.808 (0.649–1.005)	0.623	0.915 (0.643–1.302)	0.218	1.324 (0.847–2.068)
Statement 4	0.981	0.997 (0.772–1.287)	0.964	0.991 (0.656–1.495)	0.028	1.794 (1.064–3.026)
Statement 5	0.000	0.608 (0.478–0.773)	0.928	1.018 (0.695–1.491)	0.897	0.969 (0.596–1.574)
Normative beliefs aspect						
Statement 1	0.000	0.612 (0.474–0.790)	0.902	0.975 (0.653–1.455)	0.746	1.088 (0.653–1.811)
Statement 2	0.067	0.799 (0.628–1.016)	0.052	0.678 (0.459–1.003)	0.09	1.539 (0.934–2.533)
Statement 3	0.006	0.724 (0.574–0.912)	0.528	0.890 (0.619–1.279)	0.965	1.011 (0.629–1.624)
Compliance motives aspect						
Statement 1	0.005	0.733 (0.590–0.909)	0.902	1.022 (0.720–1.452)	0.629	0.895 (0.571–1.402)
Statement 2	0.084	0.804 (0.628–1.030)	0.711	0.927 (0.620–1.386)	0.693	1.109 (0.664–1.854)
Statement 3	0.400	0.917 (0.748–1.123)	0.598	0.914 (0.654–1.277)	0.305	0.802 (0.525–1.223)
Statement 4	0.301	0.874 (0.677–1.128)	0.078	1.452 (0.959–2.199)	0.281	1.334 (0.790–2.254)
Statement 5	0.003	0.725 (0.587–0.895)	0.164	0.785 (0.558–1.104)	0.846	1.045 (0.670–1.629)
Statement 6	0.088	0.830 (0.670–1.028)	0.174	0.786 (0.555–1.112)	0.961	0.989 (0.636–1.537)
Statement 7	0.204	0.855 (0.671–1.089)	0.694	0.924 (0.623–1.370)	0.601	1.143 (0.693–1.886)
Personal interests aspect						
Statement 1	0.000	0.656 (0.522–0.825)	0.584	0.903 (0.626–1.302)	0.752	0.918 (0.572–1.475)
Statement 2	0.560	0.938 (0.758–1.162)	0.749	0.945 (0.668–1.337)	0.307	0.796 (0.513–1.234)
Statement 3	0.829	0.973 (0.760–1.246)	0.394	0.838 (0.557–1.259)	0.085	1.576 (0.939–2.644)
Statement 4	0.571	0.932 (0.729–1.190)	0.971	1.007 (0.680–1.491)	0.222	1.371 (0.827–2.272)
Statement 5	0.186	0.856 (0.679–1.078)	0.290	0.819 (0.566–1.186)	0.120	1.463 (0.906–2.361)

Grey shadings show cells with a $P < 0.05$. OR=Odds ratio, CI=Confidence interval

clinical trial units strategize and develop the best approach to increase people’s participation and encourage more clinical trials.

Studies on willingness/intention to participate and perception of clinical trials have been done in various populations, which gave us a glance at the attitude toward

clinical trials, specifically on vaccine clinical trials. A study in Nepal showed that people’s acceptance of vaccine clinical trials was 67.7%.^[16] As much as 64.34% of respondents were willing to participate in vaccine clinical trials in Atlanta, US.^[17] In Germany, a planned phase 1 for the SARS-CoV-2 vaccine candidate attracted 1568 volunteers, or 62%, in the first 3 days following the first press release.^[18] A lower

Table 3c: Odds of commuting time, previous participation, and source information for positive attitude toward clinical trial

Variables	Commuting time		Previous participation		Source of information	
	Significant	OR (95% CI)	Significant	OR (95% CI)	Significant	OR (95% CI)
Behavioural perspective aspect						
Statement 1	0.736	0.954 (0.726–1.254)	0.146	0.673 (0.395–1.148)	0.210	0.891 (0.745–1.067)
Statement 2	0.412	1.122 (0.852–1.479)	0.038	0.568 (0.333–0.970)	0.448	0.932 (0.776–1.119)
Statement 3	0.747	1.042 (0.811–1.339)	0.108	0.699 (0.410–1.092)	0.527	0.948 (0.802–1.119)
Statement 4	0.251	0.843 (0.629–1.129)	0.638	1.147 (0.647–2.036)	0.420	0.923 (0.761–1.121)
Statement 5	0.646	0.938 (0.715–1.231)	0.029	0.561 (0.333–0.943)	0.175	0.882 (0.735–1.058)
Normative aspect						
Statement 1	0.553	0.918 (0.690–1.220)	0.054	0.581 (0.335–1.008)	0.438	0.928 (0.769–1.120)
Statement 2	0.553	1.086 (0.827–1.426)	0.585	0.866 (0.515–1.454)	0.527	0.943 (0.786–1.131)
Statement 3	0.309	0.873 (0.672–1.134)	0.406	0.810 (0.492–1.333)	0.034	0.828 (0.695–0.986)
Compliance motive aspect						
Statement 1	0.043	0.770 (0.597–0.992)	0.996	1.001 (0.618–1.621)	0.825	0.982 (0.833–1.157)
Statement 2	0.915	1.016 (0.763–1.352)	0.035	0.557 (0.323–0.961)	0.156	0.871 (0.720–1.054)
Statement 3	0.273	1.144 (0.900–1.454)	0.841	1.049 (0.660–1.666)	0.146	1.125 (0.960–1.319)
Statement 4	0.666	0.937 (0.698–1.259)	0.434	0.800 (0.458–1.399)	0.548	0.942 (0.775–1.145)
Statement 5	0.567	1.075 (0.839–1.378)	0.843	1.049 (0.653–1.684)	0.405	0.932 (0.790–1.100)
Statement 6	0.909	1.015 (0.789–1.305)	0.305	0.781 (0.487–1.252)	0.696	1.034 (0.874–1.223)
Statement 7	0.725	1.052 (0.794–1.392)	0.033	0.566 (0.335–0.956)	0.104	0.856 (0.710–1.032)
Personal interest aspect						
Statement 1	0.501	1.095 (0.841–1.424)	0.644	1.122 (0.688–1.830)	0.336	0.918 (0.772–1.093)
Statement 2	0.822	0.972 (0.760–1.244)	0.496	0.854 (0.541–1.346)	0.311	0.918 (0.778–1.083)
Statement 3	0.238	1.189 (0.892–1.587)	0.074	0.604 (0.347–1.051)	0.043	0.819 (0.675–0.994)
Statement 4	0.644	0.936 (0.707–1.239)	0.069	0.614 (0.363–1.038)	0.035	0.818 (0.678–0.986)
Statement 5	0.628	0.936 (0.717–1.222)	0.303	0.761 (0.453–1.279)	0.250	0.902 (0.756–1.075)

Grey shadings show cells with a $P < 0.05$. OR=Odds ratio, CI=Confidence interval

number was shown by a study in Seoul, South Korea, where only 39.3% of participants were willing to participate in a clinical trial.^[6] This study did not examine how many Indonesian people were ready to join a vaccine trial. We only studied those already participating in the trial for their attitude toward it. However, another study in the Indonesian population was performed to determine the willingness to participate in a Zika vaccine trial in children. It showed that most participants (84.1%) were willing and had a good attitude toward vaccine trials.^[19]

Characteristics of individuals in Germany's population interested in participating in clinical trials are primarily men and under 60-year-old.^[18] Echoru *et al.*, did research in Uganda, and reported that male subjects, students and civil servants, participants who were not married, and those who had no salary were more likely to participate in clinical trials.^[20] It is similar to our study, which was dominated mainly by men and those who are single. Women's participation is lower in our study, perhaps partly due to relational autonomy, in which they had to ask permission from their spouse or senior family members before participation.^[10] In our study, there was more employee than nonemployee, despite the availability time of nonemployee. The nonemployee, primarily daily-income earners, might find it difficult to leave work because they fear losing income. Respondents from lower economic and education levels dominated our study, similar to those in Portugal, but in contrast to those in Brazil, where participants from

higher economic status were more likely to participate.^[21,22] Apparently, those with low economic status and education level were more reachable and easier to be asked to join the trial in Indonesia.

The lower education level is associated with a more positive attitude toward vaccine clinical trials. It is contradictory with most other studies, for example, those by Dayer *et al.*, where the mainly university-educated respondents (80%) showed that higher education showed a better attitude.^[23] It is speculated that people with lower education have less knowledge of vaccine trials, thus, would trust the clinical trial investigators more and follow the trial protocols.

Respondents with fewer or no previous participation in clinical trials seemed to have a more positive attitude, as shown by higher Likert scores on items mentioning the benefit of the trial to protect the family, belief in the product's safety, and showed better compliance. This finding is interesting because, in a study by Appeaning *et al.*, the results were different, in which previous participation would lead to a more positive attitude.^[24] The explanation for this finding could be due to the relatively few respondents who had previous participation compared to those who have not. Another possible explanation is people without prior experience will have fewer expectations of how a trial will go, so that they will show a more positive attitude.

The source of the information of the trial affected a positive attitude. Respondents who got the information from public health centers or the head of the village showed a more positive attitude, believing more in the safety and efficacy of the product. A study by De-Los-Rios-Pinto *et al.* mentioned that having medical-related sources of information leads to participating in vaccine clinical trials.^[17] The primary health center, or Puskesmas in Indonesia, was owned by the government, so it is in line with the findings that respondents who got the information from Puskesmas also have interests in contributing to the government's program.

Altruism, defined as the desire to help others, help the future of clinical trials, and contribute to the development of medicine, was the second strongest motivation for joining the clinical trial.^[25] Motivation toward collective benefits of vaccination had been perceived by the participants in the HIV vaccine trial, who mentioned that society and the next generation would benefit from the new vaccine being developed.^[26] In our study, respondents with lower education, who are nonemployee, and those who got the information from primary health centers or authorities, seemed to show more altruistic attitudes, as indicated by the statements in behavioral perspectives 1 and 2 and personal interest 3 and 4.

Financial compensation motivates healthy volunteers to participate in a clinical study.^[22] Reward in the form of money was considered the most common motivation, both as the primary motivation and an important or essential motivation to participate in a clinical trial.^[27] Our study showed that only a lower education level was related to the attitude of joining the trial for its compensation. It is in line with the survey of Almeida *et al.* that low education levels and socioeconomic status are the shared drives for financial motivation to participate in a clinical trial.^[21] However, monthly income was not related, as also shown by another research on the Indonesian population, where the monthly income was not associated with the willingness to participate, and 37.7% of the participants remained unwilling to participate even with the highest compensation.^[19]

This study has some limitations. First, constructing the questionnaire based on a literature study, and not followed by qualitative or in-depth interviews, could only provide the view of the population from the established factors. Second, the study is limited to participation during the COVID-19 pandemic and for the COVID-19 vaccine. The urge and situations of the pandemic might influence the attitude toward vaccine clinical trials compared to

nonpandemic vaccine clinical trials. The third is the lack of representation, especially regarding ethnicities and religions. The nonheterogeneous sampling may be due to the site of clinical trials, which is mainly in Central Java. This may not cover the difference in norms and behavioral beliefs of Indonesia's cultural or religious elements. Finally, while the survey was delivered through self-reporting, some were accompanied by the researchers, which may lead to biased answers.

CONCLUSION

There was a positive attitude toward vaccine clinical trials in the Indonesian population. The positive attitude could be driven by having a low education level, nonemployment status, fewer or no previous participation in the clinical trial, and getting information from the public health centers.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Team VGCVT. COVID-19 Vaccine Tracker: Indonesia; 2022. Available from: <https://covid19.trackvaccines.org/country/indonesia/>. [Last accessed on 2022 Nov 10].
2. National Institute of Health; 2023. Available from: <https://clinicaltrials.gov/ct2/results?cond=COVID-19&term=vaccine&cntry=ID&state=&city=&dist=>. [Last accessed on 2023 May 10].
3. Trauth JM, Musa D, Siminoff L, Jewell IK, Ricci E. Public attitudes regarding willingness to participate in medical research studies. *J Health Soc Policy* 2000;12:23-43.
4. Umscheid CA, Margolis DJ, Grossman CE. Key concepts of clinical trials: A narrative review. *Postgrad Med* 2011;123:194-204.
5. McKinney M, Bell R, Samborski C, Attwood K, Dean G, Eakle K, *et al.* Clinical trial participation: A pilot study of patient-identified barriers. *Clin J Oncol Nurs* 2021;25:647-54.
6. Choi YJ, Beck SH, Kang WY, Yoo S, Kim SY, Lee JS, *et al.* Knowledge and perception about clinical research shapes behavior: Face to face survey in Korean general public. *J Korean Med Sci* 2016;31:674-81.
7. De-Los-Rios-Pinto A, Fernandez-Guzman D, Soriano-Moreno DR, Sangster-Carrasco L, Morocho-Alburqueque N, Pinedo-Soria A, *et al.* Factors associated with the intention to participate in COVID-19 vaccine clinical trials: A cross-sectional study in Peru. *Vaccine* 2022;40:3566-72.
8. Abdelhafiz AS, Abd ElHafeez S, Khalil MA, Shahrouri M, Alosaim B, Salem RO, *et al.* Factors influencing participation in COVID-19 clinical trials: A multi-national study. *Front Med (Lausanne)* 2021;8:608959.
9. Williams RJ, Tse T, DiPiazza K, Zarin DA. Terminated trials in the ClinicalTrials.gov results database: Evaluation of availability of primary outcome data and reasons for termination. *PLoS One* 2015;10:e0127242.

10. Chaudhari N, Ravi R, Gogtay NJ, Thatte UM. Recruitment and retention of the participants in clinical trials: Challenges and solutions. *Perspect Clin Res* 2020;11:64-9.
11. National Academies of Sciences E, and Medicine. *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*. Washington DC: National Academies Press (US); 2022.
12. Frew PM, Hou SI, Davis M, Chan K, Horton T, Shuster J, *et al.* The likelihood of participation in clinical trials can be measured: The clinical research involvement scales. *J Clin Epidemiol* 2010;63:1110-7.
13. World Health Organization. *Number of Clinical Trials by Year, Country, WHO Region and Income Group (1999-2021)*; 2022. Available from: <https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-clinical-trials-by-year-country-who-region-and-income-group>. [Last accessed on 2022 Nov 22].
14. Raosoft. *Sample Size Calculator*; 2022. Available from: <http://www.raosoft.com/samplesize.html>. [Last accessed on 2022 Nov 21].
15. Ekezie W, Vaz L, Czynnikowska B, Akroyd C, Davies M, Khunti K. *Understanding the Factors Associated with Willingness to Participate in a COVID-19 Vaccine Clinical Trial*. United Kingdom, London: NIHR Applied Research Collaboration East Midlands; 2020.
16. Chapagain RH, Adhikari S, Giri BR, Ray P, Shrestha NJ, Prajapati B, *et al.* Factors affecting willingness to participate in vaccine clinical trials in an underdeveloped country: Perspective from Nepal. *Hum Vaccin Immunother* 2022;18:e2051413.
17. Raheja D, Davila EP, Johnson ET, Deović R, Paine M, Roupheal N. Willingness to participate in vaccine-related clinical trials among older adults. *Int J Environ Res Public Health* 2018;15:1743.
18. Shamsrizi P, Kramer FJ, Addo MM, Fathi A. Characterization of individuals interested in participating in a phase I SARS-CoV-2 vaccine trial. *Vaccines (Basel)* 2021;9:1208.
19. Harapan H, Mudatsir M, Yufika A, Nawawi Y, Wahyuniati N, Anwar S, *et al.* Willingness to participate and associated factors in a Zika vaccine trial in Indonesia: A cross-sectional study. *Viruses* 2018;10:648.
20. Echoru I, Ajambo PD, Keirania E, Bukenya EE. Sociodemographic factors associated with acceptance of COVID-19 vaccine and clinical trials in Uganda: A cross-sectional study in western Uganda. *BMC Public Health* 2021;21:1106.
21. Almeida L, Azevedo B, Nunes T, Vaz-da-Silva M, Soares-da-Silva P. Why healthy subjects volunteer for phase I studies and how they perceive their participation? *Eur J Clin Pharmacol* 2007;63:1085-94.
22. Nappo SA, Iafate GB, Sanchez ZM. Motives for participating in a clinical research trial: A pilot study in Brazil. *BMC Public Health* 2013;13:19.
23. Dayer JA, Siegrist CA, Huttner A. Volunteer feedback and perceptions after participation in a phase I, first-in-human Ebola vaccine trial: An anonymous survey. *PLoS One* 2017;12:e0173148.
24. Appeaning M, Owusu-Asante H, Kwofie S, Arhin G, Asamoah AO, Ali T, *et al.* Improving community participation in clinical trials in Ghana; factors to consider. *Contemp Clin Trials Commun* 2022;30:101012.
25. Manton KJ, Gauld CS, White KM, Griffin PM, Elliott SL. Qualitative study investigating the underlying motivations of healthy participants in phase I clinical trials. *BMJ Open* 2019;9:e024224.
26. Tarimo EA, Ambikile J, Munseri P, Bakari M. Perception of potential harm and benefits of HIV vaccine trial participation: A qualitative study from urban Tanzania. *PLoS One* 2019;14:e0224831.
27. Grady C, Bedarida G, Sinaï N, Gregorio MA, Emanuel EJ. Motivations, enrollment decisions, and socio-demographic characteristics of healthy volunteers in phase 1 research. *Clin Trials* 2017;14:526-36.