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보건학석사학위논문

Recognition study on the value of  
a vaccine clinical trial in South  
Korea

국내 백신 임상 시험 가치에 대한 인지도 조사

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서울대학교 보건대학원

보건학과 보건학전공

오용호

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Abstract

# Recognition study on the value of a vaccine clinical trial in South Korea

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## Objective

The subjects' participation is essential in the clinical trials. However an insufficient number of studies have compared recognition of the value of clinical trials between those who have and have not participated in South Korea. The objectives of this study were to investigate differences in clinical trial recognition based on gender and to examine differences in clinical trial value

recognition and future clinical trial participation between subjects who had and had not participated in a clinical trial.

## **Methods**

To investigate the degree of recognition of the value of clinical trials in trial participants and nonparticipants in South Korea, A total of 150 participants were selected for this study. Forty-nine of 50 subjects who participated in the MTA52 study at Severance Hospital, Shinchon, (group I) completed the survey during their last visit to the study site. According to participation of MTA52 study, group I was composed of an unequal gender ratio of 17 men to 32 women. To match this gender ratio, 35 men and 65 women who had not participated in a clinical trial (group II) were recruited. All surveys were completed between September and November 2012.

## **Results and Discussion**

In this study, we found no significant gender-based difference between groups I and II. Differences in recognition of the value of clinical trials affected trial participation. Subjects in groups I and II had notably different reasons for willingness or unwillingness to participate in a clinical trial ( $P < 0.0001$ ). Group I provided positive responses, such as getting a vaccine (77.6%), receiving benefits (55.1%), participating in medical development (51.0%), and obtaining better medical services (49.0%). In contrast, group II had negative feelings about side effects (adverse events; 54.0%) and

fear about participating in clinical trials (39.0%). Reasons for subjects' willingness or unwillingness to recommend clinical trial participation to family member and/or friends also differed notably between groups ( $P < 0.0001$ ). Most (67.3%) subjects in group I but only 12.0% of those in group II had family members and/or friends who had participated in a clinical trial, whereas 16.0% of subjects in group I and 88.0% of those in group II did not ( $P < 0.0001$ ). And the participation of family members and/or friends in clinical trials had a considerable impact on subjects' own participation in both groups. No difference in subjects' reported knowledge about clinical trials was observed between groups. These results suggest that not only focusing on the benefits of participating in clinical trials, but also providing education to improve individuals' knowledge, understanding, and recognition of the safety of clinical trials are necessary. Such education would enable people to recognize the value of clinical trials and guide their decisions about whether participating in future trials could lead to the establishment of a better clinical trial environment. In addition, the sharing of government institutions' evaluations of and opinions about clinical trials with nonparticipants would alleviate anxiety and fear by providing with credible and correct information.

Although this study has small number of subjects that limiting our ability to achieve our objectives but valuable data were nonetheless obtained.

**Keywords:** Clinical trial, Participation, Patient recognition, Patient perception, Understanding, Patient benefit

**Student number:** 2010-23819

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# Chapter I. Introduction

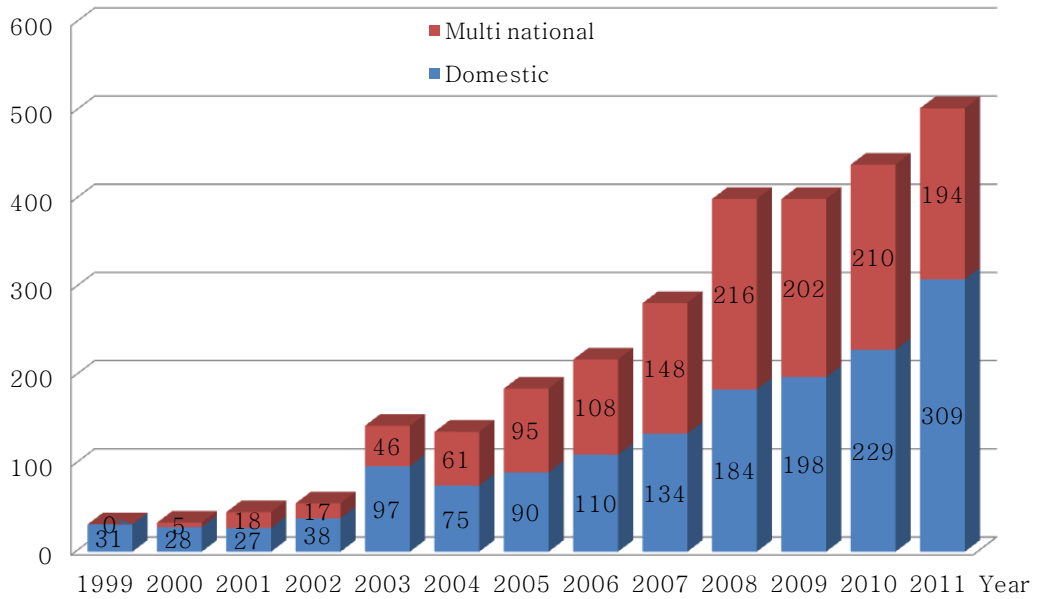
## 1. Background

A clinical trial refers to an experiment or study that is performed in humans for the purpose of demonstrating the safety and efficacy of a drug [1, 25]. Clinical trials are essential for measuring the scientific performance of a drug and provide an objective measure of new therapeutic approaches. To accomplish this, the subjects' participation is essential [2, 12]. Furthermore, the increased cost of new drug development in developed countries and the rapid economic growth and infrastructure improvement in developing countries have dramatically changed the progress achieved in clinical trials. The number of clinical trials performed in North America, Western Europe, and Japan has decreased, but clinical trials are increasingly performed in Asia, Eastern Europe, South America, Oceania, the Middle East, and Africa [3].

Clinical trials consist of four phases. In phase I, a clinical pharmacology trial is performed to determine the toxicity, absorption, metabolism, excretion, and pharmacological action of a drug in a small number of healthy people, generally 20– 80 but sometimes fewer individuals. In phase II, a therapeutic research trial is performed to demonstrate the effectiveness and safety of the drug by determining dosage and methods of administration. Most phase II trials include 100– 200 participants, but some trials evaluating multiple indications require a larger number of patients. In phase III, a therapeutic evidence clinical trial is performed after

the effectiveness of the product has been established. Phase III is the last step before licensure is granted. In this phase, control and experimental groups are used to simultaneously compare and evaluate dosage, effects, efficacy, and safety of the drug. The target number of participants varies depending on the characteristics of the drug, and is generally considered optimal when side effects are observed in 1/1000 participants. In phase IV, a post-licensure therapeutic use clinical trial is conducted to evaluate the long-term effectiveness and safety of the drug, for the purpose of obtaining additional information about side effect frequency and documenting unexpected pharmacological actions. During this phase, surveillance research is also conducted to review the morbidity and mortality rates associated with use of the drug [4, 5, 29].

Clinical trial development in South Korea has shown ongoing improvement in the past decade. In 2006, Seoul, South Korea, was ranked 20th globally in terms of the number of clinical trials performed. In 2010, Seoul was ranked 2nd [4] and the Korean Federal Drug Administration (KFDA) reported that the number of approved clinical trials in 2011 increased 14.6% from the previous year, with a total of 503 trials in 2011 and 439 in 2010 (Figure 1) [5].



<Figure 1.> Number of Clinical trial approved by KFDA (2011, Food&Drug statistical yearbook Source: KFDA, Clinical Trials Management Division) [28]

To ensure the safety of subjects, Europe mandates compliance with Good Clinical Practice and many institutes in the United States are following suit. Because all standards must be met when submitting clinical trial-related documents to a regulatory authority, elements of Good Clinical Practice such as production, performance, record keeping, and reports on subjects must be enforced [14, 15, 16]. To improve Korean clinical trials, South Korea has adjusted the Korean Good Clinical Practice guidelines to align with those of the International Conference on Harmonization. Currently, 142 hospitals have been designated as clinical trial organizations by the KFDA and are striving not only to perform clinical trials, but also to improve the quality of clinical trials performed in Korea [6].

Despite these improvements in South Korea, the false perception that clinical trials are biased in terms of participants' education level and age persists [7]. Outside Korea, older men with lower education levels and socioeconomic status have been reported to be more willing to participate in randomized clinical trials [22, 23, 24]. The claim that altruism is the only motivation for clinical trial participation is also controversial [17], as studies have shown that personal benefits, such as access to new medical treatments or nursing care [2, 18], are more common motivations than altruistic reasons [21]. Regardless of the outcome, participants in clinical trials feel that they have benefited [8], and this experience makes them more likely to participate in subsequent trials [9, 11, 26]. However, many potential subjects do not participate in clinical trials because they feel anxiety about medical treatment and find it difficult to reconcile increased potential risks and side effects with any benefit that could be gained [10, 27].

## 2. Objectives

Despite the dramatic recent improvement in clinical trial performance in South Korea [4], an insufficient number of studies have compared recognition of the value of clinical trials between those who have and have not participated. A 2008 study reported that ordinary people in South Korea continue to have negative opinions about clinical trials [7]. Prior to initiating the present study, we verbally questioned and/or submitted written questionnaires to 10 subjects who had never participated in a clinical trial. In this pilot group, 90% of subjects cited anxiety and side effects as reasons for nonparticipation. However, when the principal investigator and study coordinator of an ongoing trial commented that they accepted the safety of the study, subjects' concerns were satisfied and they expressed interest in participating in upcoming studies. Thus, subjects clearly required a scientific rationale to trust the value of a study, although no scientific investigation was conducted. The current survey-based study was conducted to gauge recognition of the value of clinical trials in people who had or had not participated in a clinical trial and to understand any potential errors and risks that could impact clinical trials in the future. The objectives of this study were to investigate differences in clinical trial recognition based on gender and to examine differences in clinical trial value recognition and future clinical trial participation between subjects who had and had not participated in a clinical trial.

## II. Study Method

### 1. Subjects

To investigate the degree of recognition of the value of clinical trials in trial participants and nonparticipants in South Korea, recruited subjects were divided into two groups. Subjects in group I had participated in the “MTA52 Clinical Trial, Safety and Immunogenicity Study for Use of Meningococcal (Group A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Adacel®) in Subjects 11 to 55 Years of Age in South Korea” [4]. The KFDA and institutional review boards (IRBs) approved this study in February 2012, and the study was conducted in accordance with the Korean Good Clinical Practices and the Declaration of Helsinki [13]. Subjects in group II were ordinary people aged  $\geq 18$  years who resided in South Korea and had not participated in a clinical trial.

The aim of the MTA52 clinical trial was to assess the safety and immunogenicity of a single dose of Menactra® in support of vaccine registration in South Korea. The primary objective of the MTA52 clinical trial was to demonstrate that seroconversion rates were  $>60\%$  in serogroups A, C, Y, and W-135 at 28 days after a single dose of Menactra®. The trial's secondary objective was to demonstrate the superiority of Menactra® over Adacel®, as determined by seroconversion rates in serogroups A, C, Y, and W-135 at 28 days after a single dose of the vaccine [4]. The trial

enrolled 300 subjects at eight study sites: 30 adolescents (aged 11–17 years) were allocated to each of five sites, and 50 adults (aged  $\geq 18$  years) were allocated to each of three sites.

For the current study, we surveyed 50 adult trial participants from the study site located at Severance Hospital, Yonsei University Health System, Shinchon, Seoul, Korea, on their last visit (group I) and 100 adults who had not participated in a clinical trial (group II). All subjects who met the inclusion and exclusion criteria provided written informed consent. In group II, only subjects who completed the anonymous survey were included in the study.



## 2. Survey Method

A questionnaire was developed after searching the PubMed, Google Scholar, National Assembly Library, and Seoul National University Library databases using terms related to clinical trial participation, including “patient recognition,” “patient perception,” “understanding,” “clinical trial,” “clinical study,” and “participation.” Two results were obtained from this search: a Korean publication entitled “Clinical Trial Awareness Survey for Patients and Legal Guardian” [7] and a foreign publication entitled “Perceived Benefit after Participating in Positive or Negative Neutral Heart Failure Trials: the Patients’ Perspectives” [8]. Questionnaire items from these sources were aggregated and those that overlapped or were deemed inadequate for our study were excluded. This process produced a 16-item survey for group I and a 15-item survey for group II, which were divided into two sections that gathered general information and information about recognition of the value of clinical trials. This survey was approved by the IRB of the Graduate School of Public Health at Seoul National University in August 2012 (IRB No. 43-2012-08-10).

The survey collected general information, including participants’ gender, year of birth, education, socioeconomic status, and religion. Clinical trial recognition information included subjects’ understanding of clinical trials, the purpose of and reason for participation in a clinical trial (group I), willingness to

participate in a clinical trial (groups I and II), likelihood of recommending participation in a clinical trial to family members and/or friends (groups I and II), and participation of family members and/or friends in a clinical trial (groups I and II) Completed questionnaires were collected and saved anonymously in the database for analysis.

### 3. Survey analysis

Survey data from each group were analyzed to evaluate differences in clinical trial value recognition based on gender, socioeconomic status, and level of education; and the groups were compared to investigate differences in clinical trial value recognition and future clinical trial participation between subjects who had and had not participated in a clinical trial.

A total of 150 participants were selected for this study. Forty-nine of 50 subjects who participated in the MTA52 study at Severance Hospital, Shinchon (group I) completed the survey during their last visit to the study site. According to participation of MTA52 study, group I was composed of an unequal gender ratio of 17 men to 32 women. To match this gender ratio, 35 men and 65 women who had not participated in a clinical trial (group II) were recruited. All surveys were completed between September and November 2012. Demographic characteristics of all study participants are shown in Table 1.

Table 1. Demographic characteristics of survey respondents

	Group			<i>P</i> -value (test)
	I	II	Total	
	( <i>n</i> = 49) <i>n</i> (%)	( <i>n</i> = 100) <i>n</i> (%)	( <i>n</i> = 149) <i>n</i> (%)	
<b>Gender</b>				
Male	17 (34.7)	35 (35.0)	52 (34.9)	0.9706 ( $\chi^2$ )
Female	32 (65.3)	65 (65.0)	97 (65.1)	
<b>Year of birth</b>	1976.6 $\pm$ 14.5	1979 $\pm$ 14		
<b>Education</b>				
High school (graduated)	10 (20.4)	3 (3.0)	13 (8.7)	0.0095 (Fisher' s exact)
University (attending)	5 (10.2)	16 (16.0)	21 (14.1)	
University (graduated)	26 (53.1)	65 (65.0)	91 (61.1)	
Graduate school (attending)	3 (6.1)	8 (8.0)	11 (7.4)	
Graduate school (graduated)	4 (8.2)	8 (8.0)	12 (8.1)	
Others	1 (2.0)	0 (0.0)	1 (0.7)	
<b>Income (Korean Won/month)</b>				
<1 million	9 (18.4)	16 (16.0)	25 (16.8)	0.8401 ( $\chi^2$ )
1–1.99 million	13 (26.5)	21 (21.0)	34 (22.8)	
2–2.99 million	9 (18.4)	24 (24.0)	33 (22.1)	
3–3.99 million	13 (26.5)	25 (25.0)	38 (25.5)	
$\geq$ 4 million	5 (10.2)	14 (14.0)	19 (12.8)	
<b>Religion</b>				
Catholic	5 (10.2)	16 (16.0)	20 (14.1)	0.2368 ( $\chi^2$ )
Christian	18 (36.7)	23 (23.0)	42 (27.5)	
Buddhist	8 (16.3)	13 (13.0)	21 (14.1)	
Other	18 (36.7)	48 (48.0)	66 (44.3)	

Values are presented as median  $\pm$  standard deviation or *n* (%)

## 4. Statistical Analysis

Quantitative variables are reported as means  $\pm$  standard deviations and categorical variables are presented as absolute and relative values (n and %). Demographic characteristics of respondents and differences in clinical trial value recognition were analyzed using chi-squared or Fisher's exact tests, as applicable. Statistical analyses were performed using SAS software (version 9.2; SAS Institute, Cary, NC, USA) and the level for significance was set at  $P < 0.005$ .

## Chapter III. Results

Gender-based differences in recognition of the value of clinical trials among subjects in group I are shown in Table 2. "Experience with a new vaccine" was the most common reason for the participation of men (52.9%) and women (65.6%) in clinical trials. The second most common reason among women was "benefits (ex: free examination, expenses for food or transportation)" (53.1%), followed by "for medical development" (25%). The second most common reason among men was "for medical development" (47.1%), followed by "for medical development and curiosity" (12.2%).

Most (82.4%) men and all women responded that they were willing to recommend clinical trial participation to family members and/or friends ( $P = 0.3667$ ). The most common reason for this answer was "experience with a new vaccine" (men, 58.8%; women, 75.0%), followed by "for medical development" in men (53.9%) and "benefits (ex: free examination, expenses for food or transportation)" in women (59.4%). The next most common answers were "benefits (ex: free examination, expenses for food or transportation)" in men (35.3%) and "to obtain better medical services" in women (56.3%). Interestingly, 41.2% of men and 15.6% of women cited "curiosity" as a reason for participation, but only 5.9% and 3.1%, respectively, cited "curiosity" as a reason for willingness to recommend clinical trial participation to family members and/or friends.

Most (88.2%) men and all women in group I expressed willingness to participate in another clinical trial ( $P = 0.1156$ ). The most commonly cited reason for this answer was "experience with a new vaccine" (men, 70.6%; women, 81.3%), followed by "for medical development" in men (52.9%) and "benefits (ex: free examination, expenses for food or transportation)" in women (59.4%). The next most common answer among men was "benefits (ex: free examination, expenses for food or transportation)" (47.1%), followed by "to obtain better medical services" (35.3%). In women, the next most common answers were "for medical development" (56.3%) and "to obtain better medical services" (50%). Most men (64.7%) and women (68.8%) had family members and/or friends who had participated in a clinical trial ( $P = 0.7738$ ).

Table 2. Gender-based differences in clinical trial participants

Questions	Responses	Men ( <i>n</i> = 17) <i>n</i> (%)	Women ( <i>n</i> = 32) <i>n</i> (%)	Total ( <i>n</i> = 49) <i>n</i> (%)	<i>P</i> -value (test)
What was (were) the reason(s) for your participation? Please check all that apply. <sup>a</sup>	For medical development	8 (47.1)	8 (25.0)	16 (32.7)	
	Curiosity	7 (41.2)	5 (15.6)	12 (24.5)	
	Benefits (ex: free examination, expenses for food or transportation)	7 (41.2)	17 (53.1)	24 (49.0)	
	Experience with a new vaccine	9 (52.9)	21 (65.6)	30 (61.2)	
	To obtain better medical services	2 (11.8)	9 (28.1)	11 (22.4)	
	Doctor' s recommendations	3 (17.6)	3 (9.4)	6 (12.2)	
	Other	0 (0.0)	0 (0.0)	0 (0.0)	
Would you be willing to recommend clinical trial participation to family members and/or friends?	Yes	14 (82.4)	32 (100)	46 (93.9)	0.3667 ( $\chi^2$ )
	No	3 (17.6)	0 (0.0)	3 (6.1)	
What is (are) the reason(s) for recommending participation to family members and/or friends? Please check all that apply. <sup>a</sup>	For medical development	9 (53.9)	13 (40.6)	22 (44.9)	
	Curiosity	1 (5.9)	1 (3.1)	2 (4.1)	
	Benefits (ex: free examination, expenses for food or transportation)	6 (35.3)	19 (59.4)	25 (51.0)	
	Experience with a new vaccine	10 (58.8)	24 (75.0)	34 (69.4)	
	To obtain better medical services	5 (29.4)	18 (56.3)	23 (46.9)	
	Other	0 (0.0)	0 (0.0)	0 (0.0)	



Would you be willing to participate in a clinical trial again?	Yes	15 (88.2)	32	47 (95.9)	0.1156 (Fisher's exact)
	No	2 (11.8)	(100.00)	2 (4.1)	
What is (are) the reason(s) for your participation? Please check all that apply. <sup>a</sup>	For medical development	9 (52.9)	16 (56.3)	25 (51.0)	
	Curiosity	5 (29.4)	4 (12.5)	9 (18.4)	
	Benefits (ex: free examination, expenses for food or transportation)	8 (47.1)	19 (59.4)	27 (55.1)	
	Experience with a new vaccine	12 (70.6)	26 (81.3)	38 (77.6)	
	To obtain better medical services	6 (35.3)	16 (50.0)	24 (49.0)	
	Other	0 (0.0)	0 (0.0)	0 (0.0)	
Do you have family members and/or friends who have participated in a clinical trial?	Yes	11(64.7)	22(68.8)	33(67.3)	0.7738 ( $\chi^2$ )
	No	6(35.3)	10(31.3)	16(16.0)	

<sup>a</sup> Some respondents had more than one answer.

Gender-based differences in clinical trial value recognition among subjects who had not participated in a clinical trial are shown in Table 3. Most men (88.6%) and women (81.5%) indicated that they would not be willing to participate in a clinical trial ( $P = 0.3602$ ). The most common reason for this answer was "side effects (adverse events)" (men, 57.1%; women, 52.3%), followed by "fear about clinical trials" (men, 37.1%; women, 40.0%). Most men (91.4%) and women (89.2%) indicated that they would not be willing to recommend clinical trial participation to family members and/or friends ( $P = 1.0000$ ), citing the same reasons given for their own unwillingness to participate: "side effects (adverse events)" (men, 62.9%; women, 63.1%) and "fear about clinical trials" (men, 45.7%; women, 46.2%). Most men (82.9%) and women (90.8%) did not have a family member and/or friend who had participated in a clinical trial ( $P = 0.3341$ ).

Table 3. Gender-based differences in clinical trial nonparticipants

Questions	Responses	Men ( <i>n</i> = 35) <i>n</i> (%)	Women ( <i>n</i> = 65) <i>n</i> (%)	Total ( <i>n</i> = 100) <i>n</i> (%)	<i>P</i> -value (test)
Would you be willing to participate in a clinical trial?	Yes	4 (11.4)	12 (18.5)	16 (16.0)	0.3602 ( $\chi^2$ )
	No	31 (88.6)	53 (81.5)	84 (84.0)	
What is(are) the reason(s) you would NOT participate in a clinical trial? Please check all that apply. <sup>a</sup>	Side effects (adverse events)	20 (57.1)	34 (52.3)	54 (54.0)	
	Current health condition is not good	4 (11.4)	4 (6.2)	8 (8.0)	
	Not interested	9 (25.7)	3 (4.6)	12 (12.0)	
	Ethical issue	0 (0.0)	4 (6.2)	4 (4.0)	
	Fear about clinical trials	13 (37.1)	26 (40.0)	39 (39.0)	
	Frequent visits to hospitals	5 (14.3)	7 (10.8)	12 (12.0)	
Other <sup>b</sup>	0 (0.0)	2 (3.1)	2 (2.0)		
Would you be willing to recommend clinical trial participation to family members and/or friends?	Yes	3 (8.6)	8 (12.3)	11 (11.0)	1.0000 (Fisher's exact)
	No	32 (91.4)	57 (87.7)	89 (89.0)	

What is(are) the reason(s) for NOT recommending participation to family members and/or friends? Please check all that apply. <sup>a</sup>	Side effects (adverse events)	22 (62.9)	41 (63.1)	63 (63.0)	
	Current health condition is not good	1 (2.9)	3 (4.6)	4 (4.0)	
	Not interested	8 (22.9)	6 (9.2)	14 (14.0)	
	Ethical issue	3 (8.6)	2 (3.1)	5 (5.0)	
	Fear about clinical trials	16 (45.7)	30 (46.2)	46 (46.0)	
	Frequent visits to hospitals	4 (11.4)	7 (10.8)	11 (11.0)	
	Other	0 (0.0)	0 (0.0)	0 (0.0)	
Do you have family members and/or friends who have participated in a clinical trial?	Yes	6 (17.1)	6 (9.2)	12 (12.0)	0.3341 (Fisher' s exact)
	No	29 (82.9)	59 (90.8)	88 (88.0)	

<sup>a</sup> Some respondents had more than one answer.

<sup>b</sup> Two respondents selected “other” and replied “required to share personal information” and “boring.”

Differences in clinical trial value recognition between subjects who had (group I) and had not (group II) participated in a clinical trial in South Korea are shown in Table 4. Most (95.9%) subjects in group I, but only 16.0% of subjects in group II, expressed willingness to participate (again) in a clinical trial, leaving 4.1% in group I and 84.0% in group II who were unwilling to participate.

Subjects in group I most commonly cited "experience with a new vaccine" (77.6%) as a reason for participation in clinical trials, followed by "benefit (ex: free examination, expenses for food or transportation)" (55.1%) and "for medical development" (51.0%). In group II, the primary reason given for not participating in clinical trials was "side effects (adverse events)" (54%), followed by "fear about clinical trials" (39.0%), "not interested" (%), and "frequent visits to hospital" (12.0%).

Table 4. Differences in recognition of the value of clinical trial participation

Questions	Responses	Group		P-value (test)
		I	II	
		(n = 49) n (%)	(n = 100) n (%)	
Would you be willing to participate in a clinical trial (again)?	Yes	47 (95.9)	16 (16.0)	<0.0001 ( $\chi^2$ )
	No	2 (4.1)	84 (84.0)	
What is (are) the reason(s) for your participation? Please check all that apply. <sup>a</sup>	For medical development	25 (51.0)	7 (7.0)	
	Curiosity	9 (18.4)	4 (4.0)	
	Benefits (ex: free examination, expenses for food or transportation)	27 (55.1)	5 (5.0)	
	Experience with a new vaccine	38 (77.6)	1 (1.0)	
	To obtain better medical services	24 (49.0)	6 (6.0)	
	Other	0 (0.0)	0 (0.0)	
What is (are) the reason(s) you would NOT participate in a clinical trial? Please check all that apply. <sup>a</sup>	Side effects (adverse events)	1 (2.0)	54 (54.0)	
	Current health condition is not good	0 (0.0)	8 (8.0)	
	Not interested	0 (0.0)	12 (12.0)	
	Ethical issue	0 (0.0)	4 (4.0)	
	Fear about clinical trials	1 (2.0)	39 (39.0)	
	Frequent visits to hospitals	0 (0.0)	12 (12.0)	
Other <sup>b</sup>	0 (0.0)	2 (2.0)		

<sup>a</sup> Some respondents had more than one answer.

<sup>b</sup> Two respondents selected “other” and replied “required to share personal information” and “boring.”

We also determined that subjects' degree of recognition of the value of clinical trials affected the perceptions of their family members and/or friends (Table 5) by asking whether they would be willing to recommend clinical trial participation to these individuals ( $P < 0.0001$ ). Most (93.9%) subjects in group I, but only 10.0% of those in group II, expressed willingness to recommend clinical trials, leaving 6.1% in group I and 90.0% in group II who were unwilling to make such a recommendation. The most commonly cited reason for willingness to recommend clinical trials in group I was "experience with a new vaccine" (69.4%), followed by "benefits (ex: free examination, expenses for food or transportation)" (51.0%), "better medical service" (46.9%) and "for medical development" (44.9%). In group II, the reasons for not recommending clinical trial participation included "side effects (adverse events)" (63.0%), "fear about clinical trials" (46.0%), and "not interested" (14.0%). The majority (67.3%) of subjects in group I, but only 12% of those in group II, had family members and/or friends who had participated in a clinical trial ( $P < 0.0001$ ), leaving 16% in group I and 88.0% in group II who did not have a close relationship with a trial participant.

Table 5. Differences in recognition of the value of clinical trial participation and recommendation of participation to family members and/or friends

Questions	Responses	Group		P-value (test)
		I (n = 49) n (%)	II (n = 100) n (%)	
Would you be willing to recommend clinical trial participation to family members and/or friends?	Yes	46 (93.9)	11 (11.0)	<0.0001 ( $\chi^2$ )
	No	3 (6.1)	89 (89.0)	
What is (are) the reason(s) for recommending participation to family members and/or friends? Please check all that apply. <sup>a</sup>	For medical development	22 (44.9)	5 (5.0)	
	Curiosity	2 (4.1)	1 (1.0)	
	Benefits (ex: free examination, expenses for food or transportation)	25 (51.0)	5 (5.0)	
	Experience with a new vaccine	34 (69.4)	1 (1.0)	
	To obtain better medical services	23 (46.9)	6 (6.0)	
	Other	0 (0.0)	0 (0.0)	
What is (are) the reason(s) for NOT recommending participation to family members and/or friends? Please check all that apply. <sup>a</sup>	Side effects (adverse events)	1 (2.0)	63 (63.0)	
	Current health condition is not good	0 (0.0)	4 (4.0)	
	Not interested	1 (2.0)	14 (14.0)	
	Ethical issue	1 (2.0)	5 (5.0)	
	Fear about clinical trials	1 (2.0)	46 (46.0)	
	Frequent visits to hospitals	0 (0.0)	11 (11.0)	
	Other <sup>b</sup>	1 (2.0)	0 (0.0)	
Do you have family members and/or friends who have participated in a clinical trial?	Yes	33 (67.3)	12 (12.0)	<0.0001 ( $\chi^2$ )
	No	16 (16.0)	88 (88.0)	

<sup>a</sup> Some respondents had more than one answer.

<sup>b</sup> One respondent selected “other” and replied “boring.”



Other differences in clinical trial value recognition between groups I and II are shown in Table 6. In group I, 46.9% of subjects indicated that they had heard and/or seen the term "clinical trial" at a hospital; 57.0% of subjects in group II had seen and/or heard the term on television. When asked how much they knew about clinical trials, 44.9% of subjects in group I claimed to have a moderate level of knowledge and 30.6% claimed to know a little; 31.0% of subjects in group II claimed to have a moderate level of knowledge and 54.0% claimed to know a little ( $P = 0.0055$ ). Subjects in both groups indicated that ordinary people (group I, 89.8%; group II, 89.0%) and patients (group I, 61.2%; group II, 75.0%) may participate in clinical trials.

When asked what types of item can be investigated in clinical trials, subjects in group I responded "medicine" (91.8%), "cytotherapy" (63.3%), "genetic therapy" (61.2%), "medical devices" (57.1%), "health care products" (42.9%), and "do not know" (4.1%); those in group II responded "medicine" (95.0%), "medical devices" (66.0%), "cytotherapy" (65.0%), "genetic therapy" (58.0%), "health care products" (38.0%), and "do not know" (1.0%).

When asked to indicate the purpose of a clinical trial, 52.1% of subjects in group I responded with both "safety examination" and "vaccination effect (efficacy) examination," and 37.5% and 10.4% of subjects provided only the former and latter responses, respectively; 67.0% of subjects in group II provided both of these responses, 25.0% indicated only "safety examination," and 7.0%

indicated only “vaccination effect (efficacy) examination” ( $P = 0.2553$ ).

For the table 2-5, to compare the table based on multiple choice, there were different type of tables appended in appendix 3. We determined that subjects’ degree of recognition of the value of clinical trials affected the perceptions of their participation and their family members and/or friends (appendix 3, Table 4, 5) by asking whether they would be willing to participate in a clinical trial (again) and recommend clinical trial participation to these individuals ( $P < 0.0001$ ). Based on multiple choice, the most cited reason for willingness to participate in clinical trials in group I was “For medical development, Benefits, Experience with a new vaccine, To obtain better medical services” (12.2%) and “To obtain better medical services” (12.5%). And not willingness to participate in clinical trials in group II was “side effects (adverse events)” (22.0%) which is the most. The most cited reason for willingness to recommend clinical trials in group I was “Experience with a new vaccine” (16.3%). And not willingness to recommend in group II was “Side effects (adverse events)” (26.0%).

Table 6. Differences in clinical trial value recognition

Questions	Responses	Group			P-value (test)
		I ( <i>n</i> = 49) <i>n</i> (%)	II ( <i>n</i> = 100) <i>n</i> (%)	Total ( <i>n</i> = 149) <i>n</i> (%)	
Have you seen or heard the term “ clinical trial ” before? If so, where? <sup>a, b</sup>	Television	15 (30.6)	57 (57.0)	72 (48.3)	
	Newspaper	6 (12.2)	13 (13.0)	19 (12.8)	
	Book	0 (0.0)	4 (4.0)	4 (2.7)	
	Hospital	23 (46.9)	34 (34.0)	57 (38.3)	
	Other	12 (24.5)	11 (11.0)	23 (15.4)	
	Never heard of it	0 (0.0)	1 (1.0)	1 (0.7)	
How much do you know about clinical trials? <sup>a</sup>	None	3 (6.1)	12 (12.0)	15 (10.1)	0.0055 (Fisher’ s exact)
	Little	15 (30.6)	54 (54.0)	69 (46.3)	
	Moderate	22 (44.9)	31 (31.0)	53 (35.6)	
	Much	5 (10.2)	3 (3.0)	8 (5.4)	
	Expert	2 (4.1)	0 (0.0)	2 (1.3)	
Who may participate in a clinical trial? Please check all that apply. <sup>a, b</sup>	Patient	30 (61.2)	75 (75.0)	105 (70.5)	
	Ordinary person	44 (89.8)	89 (89.0)	133 (89.3)	
	Animal	28 (57.1)	70 (70.0)	98 (65.8)	
	Plant	3 (6.1)	24 (24.0)	27 (18.1)	
	Do not know	2 (4.1)	3 (3.0)	5 (3.4)	
What type(s) of item can be investigated in a clinical trial? Please check all that	Medicine	45 (91.8)	95 (95.0)	140 (94.0)	
	Medical device	28 (57.1)	66 (66.0)	94 (63.1)	
	Health care product	21 (42.9)	38 (38.0)	59 (39.6)	

apply. <sup>a, b</sup>	Cytherapy	31 (63.3)	65 (65.0)	96 (64.4)	
	Genetic therapy	30 (61.2)	58 (58.0)	88 (59.1)	
	Do not know	2 (4.1)	1 (1.0)	3 (2.0)	
What is the purpose of a clinical trial? <sup>a</sup>	Safety examination	18 (37.5)	25 (25.0)	43 (29.1)	0.2553 (Fisher' s exact)
	Vaccination effect (efficacy)	5 (10.4)	7 (7.0)	12 (8.1)	
	examination	25 (52.1)	67 (67.0)	92 (62.2)	
	Both	0 (0.0)	1 (1.0)	1 (0.7)	
	Do not know				

<sup>a</sup> Two respondents in group I did not answer this question.

<sup>b</sup> Some respondents had more than one answer.

## IV. Discussion

In this study, we found no significant gender-based difference between groups I and II for the following items: willingness to recommend clinical trial participation to family members and/or friends ( $P = 0.3667$  and  $P = 1.0000$ , respectively), family members and/or friends who have participated in a clinical trial ( $P = 0.7738$  and  $P = 0.3341$ , respectively), and willingness to participate in a clinical trial ( $P = 0.3602$ ).

Differences in recognition of the value of clinical trials affected trial participation in South Korea. Subjects in groups I and II had notably different reasons for willingness or unwillingness to participate in a clinical trial ( $P < 0.0001$ ). Trial participants provided positive responses, such as getting a vaccine (77.6%), receiving benefits (55.1%), participating in medical development (51.0%), and obtaining better medical services (49.0%). In contrast, people who had not participated in a clinical trial had negative feelings about side effects (adverse events; 54.0%) and fear about participating in clinical trials (39.0%).

Reasons for subjects' willingness or unwillingness to recommend clinical trial participation to family member and/or friends also differed notably between groups ( $P < 0.0001$ ). Most (67.3%) subjects in group I but only 12.0% of those in group II had family members and/or friends who had participated in a clinical

trial, whereas 16.0% of subjects in group I and 88.0% of those in group II did not ( $P < 0.0001$ ). The participation of family members and/or friends in clinical trials had a considerable impact on subjects' own participation in both groups.

No difference in subjects' reported knowledge about clinical trials was observed between groups. The overwhelming majority (95.9%) of subjects who had participated in a clinical trial had a positive attitude toward participation in another trial and recommending participation to family members and/or friends. We also observed that participation in a clinical trial alleviated concerns about side effects and generalized fear. Those who had not participated in a clinical trial showed a negative attitude about side effects (63.0%) and fear about clinical trials (46.0%), but clinical trial value recognition did not differ significantly.

These results suggest that not only focusing on the benefits of participating in clinical trials, but also providing education to improve individuals' knowledge, understanding, and recognition of the safety of clinical trials are necessary. Such education would enable people to recognize the value of clinical trials and guide their decisions about whether participating in future trials could lead to the establishment of a better clinical trial environment. In addition, the sharing of government institutions' evaluations of and opinions about clinical trials with nonparticipants would alleviate anxiety and fear by providing with credible and correct information.

This study has some limitations. Few studies have evaluated clinical trial value recognition in people who have and have not participated not only in vaccine trials, but also in those related to oncology, cardiovascular diseases, and diabetes. Because vaccine clinical trials differ from those with other indications, additional studies including a wider range of trial types are necessary. Additionally, the number of subjects in this study was small, limiting our ability to achieve our objectives but valuable data were nonetheless obtained. Furthermore the survey did not contain many specific questions that documented clinical trial value recognition processes. Thus, additional studies with more specific questions related to this concern should be conducted. A survey-based study of clinical trial participants before and after trial completion would also be useful.

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# 국 문 초 록

## 국내 백신 임상 시험 가치에 대한 인지도 조사

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### 연구목적

임상 시험에서 피험자의 참여는 필수적이지만 한국 내에서 임상 시험에 참여 하였거나 참여하지 않은 대상자 사이에 임상 시험 가치 인지도에 대한 연구들은 충분치 않았다. 본 연구의 목적은 임상 시험에 참여하였거나 참여하지 않은 대상자들 사이에 성별에 따른 임상 시험 인지도에 차이를 조사하고 임상 시험 가치 인지도와 향후 임상 시험참여에 대하여 차이를 조사를 하는 것이다.

### 연구 방법

한국에서 임상 시험 참여한 대상자와 참여하지 않은 대상자들의 임상 시험 가치 인지도 차이를 조사하기 위해서, 본 연구에서 총 150명의 대상자가 선정 되었다. 서울 신촌에 위치한 세브란스 병원에서 MTA52 연구에 참여한 50명의 대상자 중 49명(그룹 I)이 세브란스 병원의 MTA52 연구 마지막 방문 시점에서 조사를 완료 하였다. MTA52 연구에 따라서 그룹 I은 남자 17명, 여자 32명으로 균등하지 않은 성비로 구성이 되었으며, 동일한 성비를 유지하기 위해서 임상

시험에 참여하지 않은 대상자(그룹 II)로는 남자 32명, 여자 65명이 모집이 되었다. 모든 조사는 2012년 9월과 11월사이에 완료 되었다.

## 연구 결과와 결론

연구에서, 그룹 I 과 그룹 II 사이의 성별에 따른 유의한 차이를 발견할 수 없었으며, 임상 시험에 가치 인지도에서의 차이들이 임상 시험 참여에 영향을 끼쳤다. 그룹 I와 II의 대상자들에서 임상 시험에 참여할 의향이 있는지 또는 없는지에 대해서 주목할만한 다른 이유들을 가지고 있었다( $P < 0.0001$ ). 그룹 I은 새로운 예방 접종(백신)을 경험(77.6%), 참가 시 있는 혜택(55.1%), 의료의 발전을 위해(51.0%), 그리고 보다 나은 의료 서비스(49.0%)와 같은 긍정적인 응답을 하였다. 대조적으로 그룹 II에서는 임상 시험의 부작용(유해사례; 54.0%) 그리고 임상 시험에 대한 막연한 두려움(39.0%)에 대하여 부정적인 감정을 나타내었다. 가족 및 지인이 임상 시험 참여를 본인이 권유할 의향이 있는지 또는 없는지에 대한 이유에 대해서도 그룹 I 과 그룹 II사이에 주목할만한 차이가 있었다( $P < 0.0001$ ). 대부분의 67.3% 의 그룹 I 대상자 그러나 오직 12.0% 의 그룹 II 대상자들이 가족 및 지인이 임상 시험에 참여하였다고 나타난 반면에 그룹 I의 16.0% 그리고 그룹 II의 88.0%가 참여하지 않았다고 답변하였다( $P < 0.0001$ ). 이 자료를 보면, 두 그룹에서 가족 및 지인이 임상 시험에 참여가 본인의 참여에 상당한 영향을 끼쳤다. 임상 시험에 대하여 나타난 지식에 대해서 두 그룹 대상자들 간의 차이가 발견되지 않았다. 이러한 결과들은 임상 시험에서 참여하는 것에 대한 혜택에만 초점을 맞추는 것뿐만이 아닌 개인들의 지식, 이해 그리고 임상 시험의 안전에 대한 인식을 향상시켜주는 교육을 제공하는 것 또한 필요하다고 제시하고 있다. 이러한 교육은 사람들이 임상 시험의 가치를 인지할 수 있게 하며, 향후 임상 시험

참여 유무 결정을 이끌어 줄 수 있으며, 더 나은 임상 시험 환경 확립을 유도해 나갈 수 있다. 추가적으로 임상 시험에 참여하지 않은 사람들과 함께 임상 시험에 대한 정부 기관의 평가와 의견들을 공유하는 것은 신뢰적인 그리고 올바른 정보를 제공함으로써 불안과 두려움을 완화시킬 수 있을 것이다.

본 연구는 비록 적은 수의 대상자로 인하여 목적을 달성을 하는데 제한이 되었지만, 그럼에도 불구하고 귀중한 연구자료를 도출하였다고 할 수 있겠다.

**주요어:** 임상 시험, 참여, 환자 인지, 환자 인식, 이해, 환자 혜택

**학 번:** 2010-23819

## Appendix

### 1. Survey Questionnaire for both group I and group II\_Kor\_10Aug2012\_v1.0\_final

<Group I>

#### 일반적 사항

※ 다음 문항을 읽으시고 해당란에 표시해 주십시오.

1. 귀하의 성별은 무엇입니까?

①남

②여

2. 귀하의 출생연도는 언제입니까?

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년

3. 귀하의 학력은 다음 중 무엇에 해당합니까?

①고졸

②대재

③대졸

④대학원재

⑤대학원졸

⑥기타

4. 귀하의 월 평균 소득수준은 다음 중 무엇에 해당합니까?

①100만원 미만

②100~199만원

③200~299만원

④300~399만원

⑤400만원 이상

5. 귀하의 종교는 다음 중 무엇에 해당합니까?

①천주교

②개신교

③불교

④기타

## 인지도 평가

※ 다음 문항을 읽으시고 해당란에 표시해 주십시오.

1. “임상 시험” 이란 용어를 어디에서 듣거나 보셨나요?

- ①TV
- ②신문
- ③책
- ④병원
- ⑤기타
- ⑥들어본 적 없음

2. 임상 시험에 대해 어느 정도 알고 있습니까?

- ①전혀 모름
- ②조금 알고 있음
- ③보통 정도 알고 있음
- ④상당히 많이 알고 있음
- ⑤매우 잘 알고 있음

3. 임상 시험 참여 가능 대상자에 대해서 모두 고르십시오.

- ①환자
- ②일반인
- ③동물
- ④식물
- ⑤모름

4. 임상 시험을 할 수 있는 것은 무엇이라고 생각하는지 모두 고르세요.

- ①의약품
- ②의료기기
- ③건강보조식품
- ④세포치료
- ⑤유전자치료
- ⑥모름

5. 임상 시험의 목적은 무엇입니까?

- ①안전성 규명
- ②예방 효과(유효성) 검정
- ③모두

④모름

6. 본인이 임상 시험에 참여한 이유에 대해서 **모두** 고르세요.

- ①의료의 발전을 위해
- ②호기심 때문에
- ③참가 시 있는 혜택(무료 검사 및/또는 식사비 및/또는 교통비 등) 때문에
- ④새로운 예방접종(백신)을 경험
- ⑤보다 나은 의료 서비스
- ⑥의료진의 권유에 의해서
- ⑦기타 \_\_\_\_\_

7. 가족 혹은 지인에게 임상 시험 참여를 권유할 의향  
(권유할 생각이 있다면,7-1작성 하여 주시고, 권유할 생각이 없다면,7-2작성 바랍니다.)

- ①있다
- ②없다

7-1. 권유할 생각이 있다면 그 이유는? **모두** 고르세요.

- ①의료의 발전을 위해
- ②호기심 때문에
- ③참가 시 있는 혜택 때문에(무료 검사 및/또는 식사비 및/또는 교통비 등)
- ④새로운 예방접종(백신)을 경험
- ⑤보다 나은 의료 서비스
- ⑥기타 \_\_\_\_\_

7-2. 권유할 생각이 없다면 그 이유는? **모두** 고르세요.

- ①임상 시험의 부작용(유해사례)
- ②현재 건강 상태가 나빠서
- ③관심이 없어서
- ④윤리적 문제 때문에
- ⑤임상 시험에 대한 막연한 두려움
- ⑥잡은 병원 방문
- ⑦기타 \_\_\_\_\_

8. 본인이 임상 시험에 다시 참가할 생각이 있나요?

(참가할 생각이 있다면,8-1작성 하여 주시고, 참가할 생각이 없다면,8-2작성 바랍니다.)

- ①있다
- ②없다



8-1. 참가할 생각이 있다면 그 이유는? 모두 고르세요.

- ①의료의 발전을 위해
- ②호기심 때문에
- ③참가 시 있는 혜택 때문에(검사 및/또는 식사비 및/또는 교통비 등)
- ④새로운 예방접종을 경험(백신)을 경험
- ⑤보다 나은 의료 서비스
- ⑥기타 \_\_\_\_\_

8-2. 참가할 생각이 없다면 그 이유는? 모두 고르세요.

- ①임상 시험의 부작용(유해사례)
- ②현재 건강 상태가 나빠서
- ③관심이 없어서
- ④윤리적 문제 때문에
- ⑤임상 시험에 대한 막연한 두려움
- ⑥잡은 병원 방문
- ⑦기타 \_\_\_\_\_

9. 주변에 가족 및 지인이 임상 시험에 참여한 경우가 있는지요?

- ①있다
- ②없다

<Group II>

일반적 사항

※ 다음 문항을 읽으시고 해당란에 표시해 주십시오.

1. 귀하의 성별은 무엇입니까?

①남

②여

2. 귀하의 출생연도는 언제입니까?

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년

3. 귀하의 학력은 다음 중 무엇에 해당합니까?

①고졸

②대재

③대졸

④대학원 재

⑤대학원 졸

⑥기타

4. 귀하의 월 평균 소득수준은 다음 중 무엇에 해당합니까?

①100만원 미만

②100~199만원

③200~299만원

④300~399만원

⑤400만원 이상

5. 귀하의 종교는 다음 중 무엇에 해당합니까?

①천주교

②개신교

③불교

④기타

## 인지도 평가

※ 다음 문항을 읽으시고 해당란에 표시해 주십시오.

1. “임상 시험” 이란 용어를 어디에서 듣거나 보셨나요?

- ①TV
- ②신문
- ③책
- ④병원
- ⑤기타
- ⑥들어본 적 없음

2. 임상 시험에 대해 어느 정도 알고 있습니까?

- ①전혀 모름
- ②조금 알고 있음
- ③보통 정도 알고 있음
- ④상당히 많이 알고 있음
- ⑤매우 잘 알고 있음

3. 임상 시험 참여 가능 대상자에 대해서 모두 고르십시오.

- ①환자
- ②일반인
- ③동물
- ④식물
- ⑤모름

4. 임상 시험을 할 수 있는 것은 무엇이라고 생각하는지 모두 고르세요.

- ①의약품
- ②의료기기
- ③건강보조식품
- ④세포치료
- ⑤유전자치료
- ⑥모름

5. 임상 시험의 목적은 무엇입니까?

- ①안전성 규명
- ②예방 효과(유효성) 검증
- ③모두
- ④모름

6. 본인이 임상 시험에 참가할 생각  
(참가할 생각이 있다면,6-1작성 하여 주시고, 참가할 생각이 없다면,6-2작성 바랍니다.)

- ①있다
- ②없다

6-1. 참가할 생각이 있다면 그 이유는? **모두** 고르세요.

- ①의료의 발전을 위해
- ②호기심 때문에
- ③참가 시 있는 혜택 때문에(검사 및/또는 식사비 및/또는 교통비 등)
- ④새로운 예방접종을 경험(백신)을 경험
- ⑤보다 나은 의료 서비스
- ⑥기타 \_\_\_\_\_

6-2. 참가할 생각이 없다면 그 이유는? **모두** 고르세요.

- ①임상 시험의 부작용(유해사례)
- ②현재 건강 상태가 나빠서
- ③관심이 없어서
- ④윤리적 문제 때문에
- ⑤임상 시험에 대한 막연한 두려움
- ⑥잘은 병원 방문
- ⑦기타 \_\_\_\_\_

7. 가족 혹은 지인에게 임상 시험 참여를 권유할 의향  
(권유할 생각이 있다면,7-1작성 하여 주시고, 권유할 생각이 없다면,7-2작성 바랍니다.)

- ①있다
- ②없다

7-1. 권유할 생각이 있다면 그 이유는? **모두** 고르세요.

- ①의료의 발전을 위해
- ②호기심 때문에
- ③참가 시 있는 혜택 때문에(검사 및/또는 식사비 및/또는 교통비 등)
- ④새로운 예방접종을 경험(백신)을 경험
- ⑤보다 나은 의료 서비스

⑥기타 \_\_\_\_\_

7-2. 권유할 생각이 없다면 그 이유는? **모두** 고르세요.

- ①임상 시험의 부작용(유해사례)
- ②현재 건강 상태가 나빠서
- ③관심이 없어서
- ④윤리적 문제 때문에
- ⑤임상 시험에 대한 막연한 두려움
- ⑥잘은 병원 방문
- ⑦기타 \_\_\_\_\_

9. 주변에 가족 및 지인이 임상 시험에 참여한 경우가 있는지요?

- ①있다
- ②없다

## 2. Survey Questionnaire for both group I and group II\_Eng\_10Aug2012\_v1.0\_final

<Group I>

### BASIC INFORMATION:

For subject who has participated in clinical trial.

1. Gender:
  - Male
  - Female
  
2. Year of birth (ex: 1980)
  - \_\_\_\_\_
  
3. What is your highest level of education?
  - High school (Graduated)
  - Undergraduate school (Current attending)
  - Undergraduate school (Graduated)
  - Graduate school (Currently attending)
  - Graduate school (Graduated)
  - Other
  
4. Which one of the followings is your approximate monthly income?
  - Under 1 Million Won (W1,000,000)
  - 1 Million Won - 1.99 Million Won
  - 2 Million Won - 2.99 Million Won
  - 3 Million Won - 3.99 Million Won
  - Over 4 Million Won
  
5. Religion
  - Catholic
  - Christian
  - Buddhist
  - Other

## RECOGNITION QUESTIONS:

1. Have you seen or heard of the term, “Clinical Trial” before? If so, where?
  - TV
  - Newspaper
  - Book
  - Hospital
  - Others
  - Never heard of it
  
2. How much do you know about clinical trials?
  - None
  - Very little
  - Moderate
  - Much
  - Expert
  
3. Who may participate in clinical trial? Please check all that apply.
  - Patient
  - Ordinary person
  - Animal
  - Plant
  - Do not know
  
4. What type(s) of item can be investigated during clinical trial? Please check all that apply.
  - Medicine
  - Medical device
  - Health care product
  - Cytotherapy
  - Genetic therapy
  - Do not know
  
5. What is the purpose of a clinical trial?
  - Safety investigation
  - Vaccination effect (efficacy) examination
  - Both
  - I don't know

6. What was (were) the reason(s) for your participation?  
Please check all that apply
- For medical development
  - Curiosity
  - Benefits (ex: free examination, expense for food or transportation)
  - Experience for new vaccine
  - To obtain better medical services
  - Doctor' s recommendation
  - Other
7. Would you be willing to recommend clinical trial participation to family members and/or friends? If so, please answer 7-1. If not, please answer 7-2.
- Yes
  - No
- 7-1. What is (are) the reason(s) for recommending participation to family members and/or friends?  
Please check all.
- For medical development
  - Curiosity
  - Benefits (ex: free examination, expense for food or transportation)
  - Experience for new vaccine
  - To obtain better medical services
  - Other
- 7-2. What is(are) the reason(s) for NOT recommending participation to family members and/or friends? Please check all.
- Side effects(adverse events)
  - Current health condition is not good
  - Not interested
  - Ethical issue
  - Fear about clinical trials
  - Frequent visits to hospitals
  - Other
8. Would you be willing to participate in a clinical trial again? If so, answer 8-1. If not, 8-2.
- Yes
  - No



8-1. What is (are) the reason(s) for your participation?  
Please check all.

- For medical development
- Curiosity
- Benefits (ex: free examination, expense for food or transportation)
- Experience for new vaccine
- To obtain better medical services
- Other

8-2. What is(are) the reason(s) you would NOT participate in a clinical trial? Please check all

- Side effects(adverse events)
- Current health condition is not good
- Not interested
- Ethical issue
- Fear about clinical trials
- Frequent visits to hospitals
- Other

9. Do you have family members and/or friends who have participated in a clinical trial?

- Yes
- No

<Group II>

**BASIC INFORMATION:**

For subject who has participated in clinical trial.

6. Gender:
  - Male
  - Female
  
7. Year of birth (ex: 1980)
  - \_\_\_\_\_
  
8. What is your highest level of education?
  - High school (Graduated)
  - Undergraduate school (Current attending)
  - Undergraduate school (Graduated)
  - Graduate school (Currently attending)
  - Graduate school (Graduated)
  - Other
  
9. Which one of the followings is your approximate monthly income?
  - Under 1 Million Won (W1,000,000)
  - 1 Million Won – 1.99 Million Won
  - 2 Million Won – 2.99 Million Won
  - 3 Million Won – 3.99 Million Won
  - Over 4 Million Won
  
10. Religion
  - Catholic
  - Christian
  - Buddhist
  - Other

## RECOGNITION QUESTIONS:

10. Have you seen or heard of the term, “Clinical Trial” before? If so, where?
- TV
  - Newspaper
  - Book
  - Hospital
  - Others
  - Never heard of it
11. How much do you know about clinical trials?
- None
  - Very little
  - Moderate
  - Much
  - Expert
12. Who may participate in clinical trial? Please check all that apply.
- Patient
  - Ordinary person
  - Animal
  - Plant
  - Do not know
13. What type(s) of item can be investigated during clinical trial? Please check all that apply.
- Medicine
  - Medical device
  - Health care product
  - Cytotherapy
  - Genetic therapy
  - Do not know
14. What is the purpose of a clinical trial?
- Safety investigation
  - Vaccination effect (efficacy) examination
  - Both
  - I don't know
15. Would you be willing to participate in a clinical trial? If so,

please answer 6-1. If not, 6-2.

- Yes
- No

6-1. What is (are) the reason(s) for your participation? Please check all.

- For medical development
- Curiosity
- Benefits (ex: free examination, expense for food or transportation)
- Experience for new vaccine
- To obtain better medical services
- Other

6-2. What is (are) the reason(s) you would NOT participate in a clinical trial? Please check all.

- Side effects(adverse events)
- Current health condition is not good
- Not interested
- Ethical issue
- Fear about clinical trials
- Frequent visits to hospitals
- Other

16. Would you be willing to recommend clinical trial participation to family members and/or friends? If so, please answer 7-1. If not, please answer 7-2.

- Yes
- No

7-1. . What is (are) the reason(s) for recommending participation to family members and/or friends?

Please check all.

- For medical development
- Curiosity
- Benefits (ex: free examination, expense for food or transportation)
- Experience for new vaccine
- To obtain better medical services
- Other

7-2. What is(are) the reason(s) for NOT recommending participation to family members and/or friends? Please check all.

- Side effects(adverse events)
- Current health condition is not good
- Not interested
- Ethical issue
- Fear about clinical trials
- Frequent visits to hospitals
- Other

9. Do you have family members and/or friends who have participated in a clinical trial?

- Yes
- No

3. Different type of tables based on multiple choice for table 2–5

Table 2. Gender-based differences in clinical trial participants

Questions	Responses	Men (n = 17) n (%)	Women (n = 32) n (%)	Total (n = 49) n (%)	P-value (test)
What was (were) the reason(s) for your participation? Please check all that apply. <sup>a</sup>	For medical development	2(11.7)	2(6.3)	4(8.2)	
	For medical development	2(11.7)		2(4.1)	
	Curiosity				
	For medical development	1(5.9)		1(2.0)	
	Curiosity				
	Benefits (ex: free examination, expenses for food or transportation)				
	Experience with a new vaccine				
	For medical development		1(3.1)	1(2.0)	
Curiosity					
Benefits (ex: free examination, expenses for food or transportation)					
Experience with a new vaccine					
To obtain better medical services					
Doctor's recommendations					
For medical development		1(5.9)		1(2.0)	

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Curiosity			
Experience with a new vaccine			
Doctor's recommendations			
For medical development	1 (5.9)		1 (2.0)
Benefits (ex: free examination, expenses for food or transportation)			
Experience with a new vaccine			
For medical development		1 (3.1)	1 (2.0)
Benefits (ex: free examination, expenses for food or transportation)			
Doctor's recommendations			
For medical development	1 (5.9)	1 (3.1)	2 (4.1)
Experience with a new vaccine			
For medical development		1 (3.1)	1 (2.0)
Experience with a new vaccine			
To obtain better medical services			
For medical development		1 (3.1)	2 (4.1)
To obtain better medical services			
Curiosity		1 (3.1)	1 (2.0)

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Curiosity Benefits (ex: free examination, expenses for food or transportation)	1 (5.9)		1 (2.0)
Curiosity Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine	1 (5.9)	3 (9.4)	4 (8.2)
Curiosity Benefits (ex: free examination, expenses for food or transportation) To obtain better medical services	1 (5.9)		1 (2.0)
Benefits (ex: free examination, expenses for food or transportation)		3 (9.4)	3 (6.1)
Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine	2 (11.7)	4 (12.5)	6 (12.2)
Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine To obtain better medical services		3 (9.4)	3 (6.1)

---

	Benefits (ex: free examination, expenses for food or transportation) To obtain better medical services		1 (3.1)	1 (2.0)	
	Benefits (ex: free examination, expenses for food or transportation) Doctor's recommendations		1 (3.1)	1 (2.0)	
	Experience with a new vaccine	1 (5.9)	6 (18.7)	7 (14.2)	
	Experience with a new vaccine To obtain better medical services	1 (5.9)	1 (3.1)	2 (4.1)	
	Experience with a new vaccine Doctor's recommendations		1 (3.1)	1 (2.0)	
	Doctor's recommendations	2 (11.7)		2 (4.1)	
Would you be willing to recommend clinical trial participation to family members and/or friends?	Yes	14 (82.4)	32 (100.0)	46 (93.9)	0.3667 ( $\chi^2$ )
	No	3 (17.6)	0 (0.0)	3 (6.1)	

What is (are) the reason(s) for recommending participation to family members and/or friends? Please check all that apply. <sup>a</sup>	For medical development	2(11.7)		2(4.1)
	For medical development	1(5.9)	1(3.1)	2(4.1)
	Curiosity			
	Benefits (ex: free examination, expenses for food or transportation)			
	Experience with a new vaccine			
	To obtain better medical services			
	For medical development	1(5.9)		1(2.0)
	Benefits (ex: free examination, expenses for food or transportation)			
For medical development	1(5.9)	2(6.3)	3(6.1)	
Benefits (ex: free examination, expenses for food or transportation)				
Experience with a new vaccine				
For medical development		5(15.6)	5(10.2)	
Benefits (ex: free examination, expenses for food or transportation)				
Experience with a new vaccine				
To obtain better medical services				
For medical development		1(3.1)	1(2.0)	

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Benefits (ex: free examination, expenses for food or transportation) To obtain better medical services			
For medical development Experience with a new vaccine	1 (5.9)		1 (2.0)
For medical development Experience with a new vaccine To obtain better medical services	2 (11.7)	1 (3.1)	3 (6.1)
For medical development To obtain better medical services	1 (5.9)	3 (9.4)	4 (8.2)
Benefits (ex: free examination, expenses for food or transportation)		3 (9.4)	3 (6.1)
Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine	2 (11.7)	3 (9.4)	5 (10.2)
Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine To obtain better medical services	1 (5.9)	3 (9.4)	4 (8.2)

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	Benefits (ex: free examination, expenses for food or transportation) To obtain better medical services		1 (3.1)	1 (2.0)	
	Experience with a new vaccine	2 (11.7)	6 (18.8)	8 (16.3)	
	Experience with a new vaccine To obtain better medical services		3 (9.4)	3 (6.1)	
Would you be willing to participate in a clinical trial again?	Yes	15 (88.2)	32 (100.0)	47 (95.9)	0.1156 (Fisher's exact)
	No	2 (11.8)	0 (0.0)	2 (4.1)	
What is (are) the reason(s) for your participation? Please check all that apply. <sup>a</sup>	For medical development	1 (5.9)	2 (6.3)	3 (6.1)	
	For medical development Curiosity	1 (5.9)	1 (3.1)	2 (4.1)	
	Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine				
	For medical development Curiosity	2 (11.7)		2 (4.1)	
	Benefits (ex: free examination, expenses				

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for food or transportation) Experience with a new vaccine To obtain better medical services		
For medical development Curiosity Experience with a new vaccine To obtain better medical services	1 (5.9)	1 (2.0)
For medical development Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine	2 (6.3)	2 (4.1)
For medical development Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine To obtain better medical services	6 (18.8)	6 (12.2)
For medical development Benefits (ex: free examination, expenses for food or transportation) To obtain better medical services	1 (3.1)	1 (2.0)

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For medical development Experience with a new vaccine	2(11.7)	1(3.1)	3(6.1)
For medical development Experience with a new vaccine To obtain better medical services	1(5.9)	2(6.3)	3(6.1)
For medical development To obtain better medical services	1(5.9)	1(3.1)	2(4.1)
Curiosity Benefits (ex: free examination, expenses for food or transportation)		2(6.3)	2(4.1)
Curiosity Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine	1(5.9)	1(3.1)	2(4.1)
Benefits (ex: free examination, expenses for food or transportation)	1(5.9)		1(2.0)
Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine	2(11.7)	2(6.3)	4(8.2)

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Benefits (ex: free examination, expenses for food or transportation)		1 (5.9)	4 (12.5)	5 (10.2)	
Experience with a new vaccine					
To obtain better medical services					
Experience with a new vaccine		1 (5.9)	5 (15.6)	6 (12.2)	
Experience with a new vaccine			2 (6.3)	2 (4.1)	
To obtain better medical services					
Do you have family members and/or friends who have participated in a clinical trial?	Yes	11 (64.7)	22 (68.8)	33 (67.3)	0.7738
	No	6 (35.3)	10 (31.3)	16 (16.0)	( $\chi^2$ )

<sup>a</sup> Some respondents had more than one answer.



Table 3. Gender–based differences in clinical trial nonparticipants

Questions	Responses	Men (n = 35) n (%)	Women (n = 65) n (%)	Total (n = 100) n (%)	P–value (test)
Would you be willing to participate in a clinical trial?	Yes	4 (11.4)	12 (18.5)	16 (16.0)	0.3602 ( $\chi^2$ )
	No	31 (88.6)	53 (81.5)	84 (84.0)	
What is(are) the reason(s) you would NOT participate in a clinical trial? Please check all that apply. <sup>a</sup>	Side effects (adverse events)	7 (20.0)	15 (23.1)	22 (22.0)	
	Side effects (adverse events)	2 (5.7)	2 (3.1)	4 (4.0)	
	Current health condition is not good				
	Side effects (adverse events)	1 (2.9)		1 (1.0)	
	Current health condition is not good				
	Fear about clinical trials				
	Frequent visits to hospitals				
Side effects (adverse events)	1 (2.9)	2 (3.1)	3 (3.0)		
Not interested					
Side effects (adverse events)	1 (2.9)		1 (1.0)		
Not interested					
Fear about clinical trials					

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Side effects (adverse events)	1 (2.9)		1 (1.0)
Not interested			
Fear about clinical trials			
Frequent visits to hospitals			
Side effects (adverse events)		1 (1.5)	1 (1.0)
Ethical issue			
Side effects (adverse events)	5 (14.3)	9 (13.8)	14 (14.0)
Fear about clinical trials			
Side effects (adverse events)	1 (2.9)	4 (6.15)	5 (5.0)
Fear about clinical trials			
Frequent visits to hospitals			
Side effects (adverse events)	1 (2.9)		1 (1.0)
Frequent visits to hospitals			
Side effects (adverse events)		1 (1.5)	1 (1.0)
Other <sup>b</sup>			
Current health condition is not good	1 (2.9)		1 (1.0)
Current health condition is not good		1 (1.5)	1 (1.0)

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	Fear about clinical trials				
	Current health condition is not good		1 (1.5)	1 (1.0)	
	Frequent visits to hospitals				
	Not interested	6 (17.1)	1 (1.5)	7 (7.0)	
	Ethical issue		1 (1.5)	1 (1.0)	
	Ethical issue		2 (3.1)	2 (2.0)	
	Fear about clinical trials				
	Fear about clinical trials	3 (8.6)	10 (15.3)	13 (13.0)	
	Fear about clinical trials	1 (2.9)		1 (1.0)	
	Frequent visits to hospitals				
	Frequent visits to hospitals		2 (3.1)	2 (2.0)	
	Other <sup>b</sup>		1 (1.5)	1 (1.0)	
Would you be willing to recommend clinical trial participation to family members and/or friends?	Yes	3 (8.6)	8 (12.3)	11 (11.0)	1.0000
	No	32 (91.4)	57 (87.7)	89 (89.0)	(Fisher's exact)

What is(are) the reason(s) for NOT recommending participation to family members and/or friends? Please check all that apply. <sup>a</sup>	Side effects (adverse events)	9 (25.7)	17 (26.2)	26 (26.0)
	Side effects (adverse events)	1 (2.9)	1 (1.5)	2 (2.0)
	Current health condition is not good			
	Side effects (adverse events)	1 (2.9)	1 (1.5)	2 (2.0)
	Not interested			
	Side effects (adverse events)	2 (5.7)	1 (1.5)	3 (3.0)
	Not interested			
	Fear about clinical trials			
	Side effects (adverse events)	1 (2.9)		1 (1.0)
Not interested				
Fear about clinical trials				
Frequent visits to hospitals				
Side effects (adverse events)		1 (1.5)	1 (1.0)	
Ethical issue				
Side effects (adverse events)	1 (2.9)	1 (1.5)	2 (2.0)	
Ethical issue				
Fear about clinical trials				
Side effects (adverse events)	4 (11.4)	15 (23.1)	19 (19.0)	

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Fear about clinical trials			
Side effects (adverse events)	2 (5.7)	3 (4.6)	5 (5.0)
Fear about clinical trials			
Frequent visits to hospitals			
Side effects (adverse events)	1 (2.9)	1 (1.5)	2 (2.0)
Frequent visits to hospitals			
Current health condition is not good		1 (1.5)	1 (1.0)
Current health condition is not good		1 (1.5)	1 (1.0)
Not interested			
Not interested	3 (8.6)	1 (1.5)	4 (4.0)
Not interested	1 (2.9)		1 (1.0)
Ethical issue			
Not interested		1 (1.5)	1 (1.0)
Fear about clinical trials			
Not interested		1 (1.5)	1 (1.0)
Frequent visits to hospitals			

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	Ethical issue	1 (2.9)		1 (1.0)	
	Fear about clinical trials				
	Fear about clinical trials	5 (14.3)	9 (13.8)	14 (14.0)	
	Frequent visits to hospitals		2 (3.1)	2 (2.0)	
Do you have family members and/or friends who have participated in a clinical trial?	Yes	6 (17.1)	6 (9.2)	12 (12.0)	0.3341 (Fisher's exact)
	No	29 (82.9)	59 (90.8)	88 (88.0)	

<sup>a</sup> Some respondents had more than one answer.

<sup>b</sup> Two respondents selected "other" and replied "required to share personal information" and "boring."

Table 4. Differences in recognition of the value of clinical trial participation

Questions	Responses	Group		P-value (test)
		I	II	
		(n = 49) n (%)	(n = 100) n (%)	
Would you be willing to participate in a clinical trial (again)?	Yes	47 (95.9)	16 (16.0)	<0.0001 ( $\chi^2$ )
	No	2 (4.1)	84 (84.0)	
What is (are) the reason(s) for your participation? Please check all that apply. <sup>a</sup>	For medical development	3 (6.1)	4 (4.0)	
	For medical development	2 (4.1)		
	Curiosity			
	Benefits (ex: free examination, expenses for food or transportation)			
	Experience with a new vaccine			
	For medical development	2 (4.1)		
	Curiosity			
	Benefits (ex: free examination, expenses for food or transportation)			
	Experience with a new vaccine			
	To obtain better medical services			
For medical development	1 (2.0)			
Curiosity				
Experience with a new vaccine				
To obtain better medical services			1 (1.0)	
For medical development	2 (4.1)			
Benefits (ex: free examination, expenses for food or transportation)				
Experience with a new vaccine				
For medical development	6 (12.2)			

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Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine To obtain better medical services		
For medical development	1 (2.0)	
Benefits (ex: free examination, expenses for food or transportation) To obtain better medical services		
For medical development	3 (6.1)	1 (1.0)
Experience with a new vaccine		
For medical development	3 (6.1)	
Experience with a new vaccine To obtain better medical services		
For medical development	2 (4.1)	1 (1.0)
To obtain better medical services		
Curiosity		2 (2.0)
Curiosity	2 (4.1)	1 (1.0)
Benefits (ex: free examination, expenses for food or transportation)		
Curiosity	2 (4.1)	
Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine		
Benefits (ex: free examination, expenses for food or transportation)	1 (2.0)	2 (2.0)
Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine	4 (8.2)	
Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine To obtain better medical services	5 (10.2)	

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	Experience with a new vaccine	6(12.2)	
	Experience with a new vaccine To obtain better medical services	2(4.1)	2(2.0)
	To obtain better medical services		2(2.0)
What is (are) the reason(s) you would NOT participate in a clinical trial? Please check all that apply. <sup>a</sup>	Side effects (adverse events)	1 (2.0)	22(22.0)
	Side effects (adverse events)		4(4.0)
	Current health condition is not good		
	Side effects (adverse events)		1(1.0)
	Current health condition is not good		
	Fear about clinical trials		
	Frequent visits to hospitals		
	Side effects (adverse events)		3(3.0)
	Not interested		
	Side effects (adverse events)		1(1.0)
	Not interested		
	Fear about clinical trials		
	Side effects (adverse events)		1(1.0)
	Not interested		
Fear about clinical trials			
Frequent visits to hospitals			
Side effects (adverse events)		1(1.0)	
Ethical issue			
Side effects (adverse events)		14(14.0)	
Fear about clinical trials			
Side effects (adverse events)		5(5.0)	
Fear about clinical trials			
Frequent visits to hospitals			
Side effects (adverse events)		1(1.0)	
Frequent visits to hospitals			
Side effects (adverse events)		1(1.0)	
Other <sup>b</sup>			

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Current health condition is not good		1 (1.0)
Current health condition is not good Fear about clinical trials		1 (1.0)
Current health condition is not good Frequent visits to hospitals		1 (1.0)
Not interested		7 (7.0)
Ethical issue		1 (1.0)
Ethical issue Fear about clinical trials		2 (2.0)
Fear about clinical trials	1 (2.0)	13 (13.0)
Fear about clinical trials Frequent visits to hospitals		1 (1.0)
Frequent visits to hospitals		2 (2.0)
Other <sup>b</sup>		1 (1.0)

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<sup>a</sup> Some respondents had more than one answer.

<sup>b</sup> Two respondents selected “other” and replied “required to share personal information” and “boring.”

Table 5. Differences in recognition of the value of clinical trial participation and recommendation of participation to family members and/or friends

Questions	Responses	Group		P-value (test)
		I (n = 49) n (%)	II (n = 100) n (%)	
Would you be willing to recommend clinical trial participation to family members and/or friends?	Yes	46 (93.9)	11 (11.0)	<0.0001 ( $\chi^2$ )
	No	3 (6.1)	89 (89.0)	
What is (are) the reason(s) for recommending participation to family members and/or friends? Please check all that apply. <sup>a</sup>	For medical development	2(4.1)	2(2.0)	
	For medical development Curiosity		1(1.0)	
	For medical development Curiosity	2(4.1)		
	Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine To obtain better medical services			
	For medical development Benefits (ex: free examination, expenses for food or transportation)	1(2.0)		
	For medical development Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine	3(6.1)		
	For medical development Benefits (ex: free examination, expenses for food or transportation) Experience with a new vaccine To obtain better medical services	5(10.2)		

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For medical development	1 (2.0)	1 (1.0)
Benefits (ex: free examination, expenses for food or transportation)		
To obtain better medical services		
For medical development	1 (2.0)	
Experience with a new vaccine		
For medical development	3 (6.1)	
Experience with a new vaccine		
To obtain better medical services		
For medical development	4 (8.2)	1 (1.0)
To obtain better medical services		
Benefits (ex: free examination, expenses for food or transportation)	3 (6.1)	2 (2.0)
Benefits (ex: free examination, expenses for food or transportation)	5 (10.2)	
Experience with a new vaccine		
Benefits (ex: free examination, expenses for food or transportation)	4 (8.2)	1 (1.0)
Experience with a new vaccine		
To obtain better medical services		
Benefits (ex: free examination, expenses for food or transportation)	1 (2.0)	1 (1.0)
To obtain better medical services		
Experience with a new vaccine	8 (16.3)	
Experience with a new vaccine	3 (6.1)	
To obtain better medical services		
To obtain better medical services		2 (2.0)

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What is (are) the reason(s) for NOT recommending participation to family members and/or friends? Please check all that apply. <sup>a</sup>	Side effects (adverse events)	26 (26.0)
	Side effects (adverse events)	2 (2.0)
	Current health condition is not good	
	Side effects (adverse events)	2 (2.0)
	Not interested	
	Side effects (adverse events)	3 (3.0)
	Not interested	
	Fear about clinical trials	
	Side effects (adverse events)	1 (1.0)
	Not interested	
	Fear about clinical trials	
	Frequent visits to hospitals	
	Side effects (adverse events)	1 (1.0)
	Ethical issue	
Side effects (adverse events)	2 (2.0)	
Ethical issue		
Fear about clinical trials		
Side effects (adverse events)	19 (19.0)	
Fear about clinical trials		
Side effects (adverse events)	5 (5.0)	
Fear about clinical trials		
Frequent visits to hospitals		
Side effects (adverse events)	2 (2.0)	
Frequent visits to hospitals		
Side effects (adverse events)	1 (2.0)	
Fear about clinical trials		
Other <sup>b</sup>		
Current health condition is not good	1 (1.0)	
Current health condition is not good	1 (1.0)	
Not interested		

	Not interested	1 (2.0)	4 (4.0)	
	Not interested		1 (1.0)	
	Ethical issue			
	Not interested		1 (1.0)	
	Fear about clinical trials			
	Not interested		1 (1.0)	
	Frequent visits to hospitals			
	Ethical issue	1 (2.0)		
	Ethical issue		1 (1.0)	
	Fear about clinical trials			
	Fear about clinical trials		14 (14.0)	
	Frequent visits to hospitals		2 (2.0)	
Do you have family members and/or friends who have participated in a clinical trial?	Yes	33 (67.3)	12 (12.0)	<0.0001 ( $\chi^2$ )
	No	16 (16.0)	88 (88.0)	

<sup>a</sup> Some respondents had more than one answer.

<sup>b</sup> One respondent selected “other” and replied “boring.”